

EPA Reg. No. 74468-12

PROCESSING REQUEST

Reg # 74468-12

Decision # 543943

Description: PR1A CSF Amendment

Electronic Label & Letter
(see PPLS):

OR

**Non Electronic
Label & Letter**
(Scanning required):

☐ Dated:

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☐ New CSF(s) Dated: Base + AH#1 dated Aug 29, 2018

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Shanta Adeeb

Division: RD/HB

Phone: 347-0502

Date: 6/19/2019



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 19, 2019

Jane M. Miller
ProActive, LLC
10529 Heritage Bay Blvd.
Naples, FL 34120

Subject: PRIA Label and CSF Amendment – Revise Basic and Alternate CSFs, Change Active Ingredient Statement from 98.2% to 98.61%, and Remove All Food Uses
Product Name: 2,4-D Acid Technical
EPA Registration Number: 74468-12
Application Date: August 29, 2018
Decision Number: 543943

Dear Ms. Miller:

The amended label and Confidential Statements of Formula (CSFs) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 08/29/2018
- Alternate CSF 1 dated 08/29/2018

Any CSFs other than those listed above are superseded/no longer valid.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced

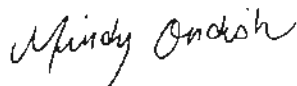
Page 2 of 2
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on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Shanta Adeeb by phone at 703-347-0502, or via email at adeeb.shanta@epa.gov.

Sincerely,



Mindy Ondish
Product Manager 23
Herbicide Branch
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

2,4-D Acid Technical

For Manufacturing Use Only

Active Ingredient:

2,4-dichlorophenoxyacetic acid98.61%

Related Ingredients:.....1.39%

Total.....100.00%

ACCEPTED

06/19/2019

Under the Federal Insecticide, Fungicide,
and Rodenticide Act as amended, for the
pesticide registered under

EPA Reg. No. **74468-12**

Keep Out of Reach of Children

DANGER

Precautionary Statements

Hazards to Humans and Domestic Animals

Corrosive. Causes irreversible eye damage. Harmful if swallowed, inhaled or absorbed through the skin.

Do not get in eyes or on clothing. Avoid contact with skin or clothing. Avoid breathing vapor. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. When handling this product, wear eye protection (safety glasses, face shield, or chemical goggles), and chemical resistant gloves (nitrile rubber or butyl rubber ≥ 14 mils). Remove and wash contaminated clothing and clean protective equipment before reuse.

First Aid	
If in eyes:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If swallowed:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If on skin or clothing:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If inhaled:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth if possible.• Call a poison control center or doctor for further treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may contact 1-800-222-1222 for emergency medical treatment information.	
Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.	

Manufacturing Chemical: Do not ship or store with food, feeds, drugs or clothing.

Environmental Hazards

This product is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Directions for Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR MANUFACTURING USE ONLY

For Formulation into Herbicides for the Following NON-CROP Use(s):

1. Turf (including Lawns, Golf Courses, Cemeteries, Parks, Airfields, Yards), Roadsides, Non-Cropland Areas including Rights-of-Way, Areas in the Conservation Reserve Program, Railroads, Drainage Ditch Banks, Fence Rows, Tree Injection Treatments, Woody Plant Control in Non-Cropland Areas; Ornamental Trees, Shrubs and Vines;

Aquatic Weed Control: agricultural irrigation water and ditches; agricultural drainage water and ditches; lakes, ponds, reservoirs, impounded water, streams, rivers, and canals; swamps, marches, wetlands, estuaries, tidal marshes; commercial and sport fish bearing waters; industrial ponds;

2. Uses for which U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration.
3. Uses for experimental purposes that are in compliance with U.S. EPA requirements.

This product may be used to formulate products for specific use(s) not listed on this label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding support of such use(s).

Formulators using this product are responsible for obtaining EPA registration for their formulated products. Contact ProActive, LLC for instructions about formulation and other information.

Wettable powder formulations must be packaged in water-soluble packages.

Storage and Disposal

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a secured area preferably cool and dry. Open containers in well ventilated areas. Keep container tightly closed when not in use. Store only in original container unless it is damaged and requires to be replaced. In such case, clearly label contents.

Pesticide Disposal: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or environmental control agency, or the hazardous waste representative at the nearest EPA Regional Office for guidance. If container is damaged or pesticide has leaked, clean up all spilled materials and place in closed labeled container.

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into manufacturing equipment by shaking and tapping sides and bottom to loosen clinging particles. Then offer for recycling, if available, or dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Warranty Limitations and Disclaimer

ProActive, LLC warrants that at the time of delivery, the product will conform to its chemical description on the label, that it will pass without objection in the trade under the contract description, that seller will convey good title thereto, and that such product will be delivered free from any lawful security interest, lien or encumbrance.

This is the only warranty made on this product. To the extent consistent with applicable law, ProActive, LLC EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND, EXCEPT AS SET FORTH IN THE ABOVE PARAGRAPH, ANY OTHER EXPRESS OR IMPLIED WARRANTIES. Buyer acknowledges the use of its own independent skill and expertise in the selection and use of the product and does not rely on any oral or written statements or representations.

EPA Reg. No. 74468-12

EPA Est. Nos. XXXXX-XXX-XXX

Net Weight: ____ lbs. (____ kg)
Batch No. [marked on container]

Manufactured for:
ProActive, LLC
10529 Heritage Bay Blvd.
Naples, FL 34120

Adeeb, Shanta

From: Adeeb, Shanta
Sent: Tuesday, June 11, 2019 12:25 PM
To: 'Larry Miller'
Cc: Ondish, Mindy; Jane Miller; [REDACTED]
Subject: RE: Correct CLEAN label for 74468-12

Good Morning Larry,

Thanks for this additional information. We will get back to you as quickly as possible about the way forward for this action.

Regards,

Shanta

From: Larry Miller <larry.miller@proactive-products.net>
Sent: Tuesday, June 11, 2019 10:25 AM
To: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Cc: Ondish, Mindy <ondish.mindy@epa.gov>; Jane Miller <jmiller@biologicconsulting.com>; [REDACTED]
Subject: RE: Correct CLEAN label for 74468-12

Good morning Shanta:

Jane ask me to respond directly to you regarding proposed amendment for EPA Reg. No. 74468-12. Please note the following:

- ✓ The registration was originally approved on August 21, 2012 as a repack of [REDACTED]
- [REDACTED]

I hope this information is helpful for you and Mindy to understand the history of this product. I'm aware of the voluntary cancellation procedures of FIFRA 6(f) and appreciate the necessity of a public comment period to allow users to respond. However, since this is a technical grade active ingredient having multiple registered sources, our registration have

[REDACTED], we are kindly requesting to amend the label for non-agricultural uses and waive public comment.

Please note we are a very small company and any delays beyond July 2019 will cause us a significant economic hardship. Thank you for your consideration.

Best Regards,

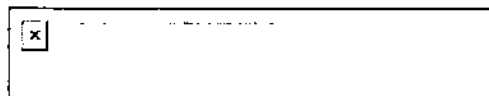
Larry

Lawrence A. Miller
PROACTIVE, LLC
10529 Heritage Bay Blvd.
Naples, FL 34120

Tel: (239) 331-3010

Mobile: (239) 238-6691

Email: larry.miller@proactive-products.net



From: Jane Miller <jmiller@biologicconsulting.com>

Sent: Monday, June 10, 2019 2:48 PM

To: Larry Miller <lmiller@biologicconsulting.com>

Subject: Fwd: Correct CLEAN label for 74468-12

Sent from my iPhone

Begin forwarded message:

From: "Adeeb, Shanta" <Adeeb.Shanta@epa.gov>

Date: June 10, 2019 at 2:22:41 PM EDT

To: Jane Miller <jmiller@biologicconsulting.com>

Cc: "Ondish, Mindy" <ondish.mindy@epa.gov>

Subject: RE: Correct CLEAN label for 74468-12

Hi Jane,

I spoke to Mindy and it looks like the removal of the Agricultural Crops and Forestry uses from this label will trigger a 6f. Can you please provide additional information about this product, including if the Agricultural Crops and Forestry uses have ever been marketed or sold. The link below describes the requirements for removing uses from products.

<https://www.epa.gov/pesticide-registration/voluntary-cancellation-pesticide-product-or-use>

Regards,

Shanta

From: Jane Miller <jmiller@biologicconsulting.com>
Sent: Thursday, June 06, 2019 12:11 PM
To: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Correct CLEAN label for 74468-12

Thank you. Anything you need, let me know.

Regards,

Jane M. Miller

BIOLOGIC REGULATORY CONSULTING, INC.
10529 Heritage Bay Blvd.
Naples, FL 34120
Tel: 239-331-3422
Cell: 239-238-6584

From: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Sent: Thursday, June 6, 2019 9:58 AM
To: Jane Miller <jmiller@biologicconsulting.com>
Subject: RE: Correct CLEAN label for 74468-12

Thanks. I will try to get this wrapped up next week.

From: Jane Miller <jmiller@biologicconsulting.com>
Sent: Thursday, June 06, 2019 9:55 AM
To: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Correct CLEAN label for 74468-12

Hi Shanta,

Attached is the correct CLEAN label for the amendment action.

Regards,

Jane M. Miller

BIOLOGIC REGULATORY CONSULTING, INC.
10529 Heritage Bay Blvd.
Naples, FL 34120

Tel: 239-331-3422
Cell: 239-238-6584

From: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Sent: Thursday, June 6, 2019 9:52 AM
To: Jane Miller <jmiller@biologicconsulting.com>
Subject: RE: Status Update for EPA Reg. No. Status of PRIA Amendment for EPA Reg. No. 74468-12

Thanks for the quick response.

From: Jane Miller <jmiller@biologicconsulting.com>
Sent: Thursday, June 06, 2019 9:48 AM
To: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Status Update for EPA Reg. No. Status of PRIA Amendment for EPA Reg. No. 74468-12

Hi Shanta,

Attached are the labels submitted with the amendment, marked and clean.

Regards,

Jane M. Miller

BIOLOGIC REGULATORY CONSULTING, INC.
10529 Heritage Bay Blvd.
Naples, FL 34120
Tel: 239-331-3422
Cell: 239-238-6584

From: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Sent: Thursday, June 6, 2019 9:11 AM
To: Jane Miller <jmiller@biologicconsulting.com>
Subject: RE: Status Update for EPA Reg. No. Status of PRIA Amendment for EPA Reg. No. 74468-12

Good Morning Jane,

The product chemistry review for this action has been completed but I just realized that the purity of the product has changed. Please send me an updated label with the purity changed to 98.61% and we can get this action closed.

Feel free to contact me if you have any questions.

Regards,

Shanta

Adeeb, Shanta

Resubmission #1

From: Jane Miller <jmiller@biologicconsulting.com>
Sent: Thursday, June 06, 2019 9:48 AM
To: Adeeb, Shanta
Subject: RE: Status Update for EPA Reg. No. Status of PRIA Amendment for EPA Reg. No. 74468-12
Attachments: 074468-00012.20180829.2,4-D Acid Technical.amended label.MARKED.V2.pdf;
074468-00012.20180829.2,4-D Acid Technical.amended label.CLEAN.V2.pdf

Hi Shanta,

Attached are the labels submitted with the amendment, marked and clean.

Regards,

Jane M. Miller

BIOLOGIC REGULATORY CONSULTING, INC.
10529 Heritage Bay Blvd.
Naples, FL 34120
Tel: 239-331-3422
Cell: 239-238-6584

From: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Sent: Thursday, June 6, 2019 9:11 AM
To: Jane Miller <jmiller@biologicconsulting.com>
Subject: RE: Status Update for EPA Reg. No. Status of PRIA Amendment for EPA Reg. No. 74468-12

Good Morning Jane,

The product chemistry review for this action has been completed but I just realized that the purity of the product has changed. Please send me an updated label with the purity changed to 98.61% and we can get this action closed.

Feel free to contact me if you have any questions.

Regards,

Shanta

From: Jane Miller <jmiller@biologicconsulting.com>
Sent: Friday, May 24, 2019 9:20 AM
To: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Status Update for EPA Reg. No. Status of PRIA Amendment for EPA Reg. No. 74468-12

Hi Shanta,

Have you heard anything back from product chemistry on this pending application?

Regards,

Jane M. Miller

BIOLOGIC REGULATORY CONSULTING, INC.
10529 Heritage Bay Blvd.
Naples, FL 34120
Tel: 239-331-3422
Cell: 239-238-6584

From: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Sent: Thursday, May 16, 2019 2:54 PM
To: Jane Miller <jmiller@biologicconsulting.com>
Subject: Status Update for EPA Reg. No. Status of PRIA Amendment for EPA Reg. No. 74468-12

Good Afternoon Ms. Miller,

I just wanted you to know that the product chemistry review for this action is *still pending* at this time. I have reached out to the product chemistry team to see if they will have the review completed by the May 28, 2019 PRIA date. Once I hear back from the team I will let you know if we are still on track to meet the current PRIA date.

Regards,

Shanta Adeeb, M.S.
Risk Manager, Herbicide Branch
Registration Division, Office of Pesticide Programs
United States Environmental Protection Agency
Number: 703-347-0502, Email: adeeb.shanta@epa.gov

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)



DOCUMENT CONTAINS CONFIDENTIAL BUSINESS INFORMATION

DP BARCODE No.: D449902; **FILE SYMBOL/REG. No.:** 74468-12 (basic CSF & altCSF#1); **PRODUCT NAME:** 2,4-D Acid Technical; **DECISION No.:** 543943; **PC Code(s):** 030001; **ACTION CODE:** R351; **FOOD Use:** No; **REGISTRANT:** ProActive, LLC

DATE: May 31, 2019

SUBJECT: Product Chemistry Review of "2,4-D Acid Technical"

FROM: Shyam Mathur
Product Chemistry Team Leader
Chemistry, Inerts & Toxicology Assessment Branch (CITAB)/RD (7505P)

A handwritten signature in black ink, appearing to read "S. Mathur", written over the printed name and title.

TO: Shanta Adeeb / Kathryn Montague, PM 23
Herbicide Branch / RD (7505P)

MRID Numbers: 50631101, 50631102, 50631103, 50631104, 50631105, 50631106, 50631107, 50631108, 50631109, 50631110, 50631111, 50631112, 50631113, 50631114, 50631115, 50631116, 50631117

INTRODUCTION:

The applicant has submitted an application to amend the registration of the subject product 2, 4-D Acid Technical. The amendment involved the submission of the revised basic CSF dated August 29, 2018

[REDACTED] The registrant has submitted Group A and Group B product chemistry data in support of the proposed basic and alternate CSF's. The current basic CSF (dated 04-27-2012) is 100% re-pack of the registered product with [REDACTED] with the product label claim of 98.2%. Primary review was performed by Summitec Corporation of Knoxville, TN, USA. CITAB has been asked to determine the acceptability of the product chemistry data and proposed basic and alternate CSFs.

SUMMARY OF FINDINGS:

1. Group A guidelines:

830.1550: (product identity & composition)

The active ingredient was adequately described (MRID 50631101). The nominal concentrations of the active ingredient listed on the proposed Basic CSF and Alternate CSF match their respective averages obtained from the five-batch preliminary analyses of the product produced at the two manufacturing sites (MRIDs 50631103 through 50631105). These nominal concentrations (98.61% on the Basic CSF and 95.75% on the Alternate CSF) are within the certified limits (lower limit: 95.65%, upper limit: 100.00%) listed on the proposed Basic CSF (dated 08/29/2018). The content of the active ingredient (98.61%) given on the proposed Basic CSF does not match that (97.5%) provided on the proposed product label.

DP BARCODE No.: D449902; **FILE SYMBOL/REG. No.:** 74468-12 (basic CSF & altCSF#1); **PRODUCT NAME:** 2,4-D Acid Technical; **DECISION No.:** 543943; **PC Code(s):** 030001; **ACTION CODE:** R351; **FOOD Use:** No; **REGISTRANT:** ProActive, LLC

The registrant has submitted a revised label with product label claim of 98.61% (non-food use only) which concurs with the nominal concentration of the AI in the revised basic CSF. The product chemistry data submitted for the guideline 830.1550 satisfy the data requirements of 40CFR§158.320.

830.1600: (description of materials used to produce the product)

Safety Data Sheets (SDSs) for all the starting materials used at both basic and alternate manufacturing sites, and their specifications and suppliers were provided in the study (MRIDs 50631101 and 50631102). The product chemistry data submitted for the guideline 830.1600 satisfy the data requirements of 40CFR§158.325

830.1620 (description of production process)

Detailed descriptions of the production processes at both basic and alternate manufacturing sites, chemical pathways, quality control measures, and flow charts were included in MRIDs 50631101 and 50631102. The product chemistry data submitted for the guideline 830.16200 satisfy the data requirements of 40CFR§158.330

830.1670. (Discussion on the formation of impurities)

Potential impurities were identified and quantified as part of the five-batch analyses for both basic and alternate manufacturing sites (MRIDs 50631103 through 50631105). The origins and identities of the impurities were fully discussed in MRIDs 50631101 and 50631102.

Impurities of toxicological concern in 2,4-D Acid Technical include Polychlorinated Dibenzodioxins (PCDDs) and Polychlorinated Dibenzofurans (PCDFs) from both manufacturing sites. No PCDD or PCDF was detected at a level above their respective limits of quantitation in the five-batch preliminary analysis of the product from either manufacturing source. [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED] The product chemistry data submitted for the guideline 830.1670 satisfy the data requirements of 40CFR§158.340

830.1700 (preliminary analysis)

Results are presented for two five-batch analyses of the product produced at both basic and alternate manufacturing sites (MRIDs 50631103 through 50631105). The nominal concentrations of the active ingredient at the Basic Source were: 98.73, 98.37, 98.75, 98.62, and 98.58% (average 98.61%, from Page 9 in MRID 50631103). [REDACTED]

_____ Certificates
of analysis for all the five batches used in the preliminary analysis were provided in MRID 50631103.

The nominal concentrations of the active ingredient at the Alternate Source were: 94.510, 96.139, 97.085, 95.918, and 95.115% (average 95.753%, from Page 27 of 203 in MRID 50631104). Note that the concentrations of the active ingredient in two of the five batches are not within the certified limits (lower limit: 95.65%, upper limit: 100.00%) listed on the proposed Basic CSF (dated 08/29/2018).

The product chemistry data submitted for the guideline 830.1700 satisfy the data requirements of 40CFR§158.345.

830.1750 (certified limits)

The nominal concentrations of the active ingredient and impurities on the proposed Basic CSF and Alternate CSF are the same as their respective averages derived from the five-batch preliminary analyses of 2,4-D Acid Technical produced at both basic and alternate manufacturing sites (MRIDs 50631103 through 50631105).

The certified limits for the active ingredient and upper certified limits for the impurities provided on the Basic CSF are consistent with those reported on Page 18 in the confidential attachment of MRID 50631101, and also are within their respective OCSPP-recommended ranges. The proposed certified limits for the impurities in the alternate CSF #1 are based on the standard certified limits as per 40CFR§158.350 (see page #17 of MRID No. 50631102). The certified limits for the other ingredients listed on the Alternate CSF are within EPA standard certified limits. The product chemistry data submitted for the guideline 830.1750 satisfy the data requirements of 40CFR§158.350.

830.1800 (enforcement analytical method)

The analytical method for quantifying the active ingredient in five representative batches of 2,4-D Acid Technical produced at the Basic Source was HPLC-UV at 230 nm with a DAD detector and external standard calibration, which was validated in terms of linearity, selectivity, accuracy (recovery), precision (repeatability), intermediate precision, LOD and LOQ (MRID 50631103). The identity of the active ingredient was confirmed by the retention time (HPLC-UV) and spectra (MS, UV, IR, and ¹H-NMR) obtained from the five batches of the test item and 2,4-D Acid analytical standard (MRID 50631103).

DP BARCODE No.: D449902; FILE SYMBOL/REG. No.: 74468-12 (basic CSF & altCSF#1); PRODUCT NAME: 2,4-D Acid Technical; DECISION No.: 543943; PC Code(s): 030001; ACTION CODE: R351; FOOD Use: No; REGISTRANT: ProActive, LLC

The analytical method for quantifying the active ingredient in five representative batches of 2,4-D Acid Technical produced at the Alternate Source was HPLC-UV at 229 nm (Method No. 510G1080A-1), which was validated for linearity, precision and accuracy (MRID 50631104). The identity of the active ingredient was confirmed using HPLC-UV/PDA, ES-MS, ¹³C-NMR and ¹H-NMR spectra analysis against 2,4-D Acid analytical standard. [REDACTED]

[REDACTED] The product chemistry data submitted for the guideline 830.1800 satisfy the data requirements of 40CFR§158.355.

2. Group B guidelines (physical-chemical properties):

The registrant provided a set of Group B product chemistry data for each manufacturing source. The relevant data for the Basic Source were included in MRIDs 50631106 through 50631117, while those for the Alternate Source were included in MRID 50631104.

Adequate data were submitted for color, physical state, odor, stability to normal/elevated temperatures and metals/metal ions, oxidation/reduction, pH, UV/Visible absorption, melting point, density, dissociation constants in water, partition coefficient, water solubility and vapor pressure (MRIDs 50631104, 50631106, 50631108, and 50631110 through 50631117). No data were provided for flammability, explosability, miscibility, viscosity, and boiling point as they are irrelevant to the product.

A 14-day accelerated storage stability study was conducted on 2,4-D Acid Technical (Batch No. 20150826) produced at the Basic Source at 54 ± 2°C (MRID 50631107). The test substance was stored in a polyethylene plastic bag (commercial packaging material). The concentration of the active ingredient was determined initially, and after 1, 2, 7, and 14 days of storage using the validated enforcement analytical method (see MRID 50631103). The results showed that the product was stable at 54 ± 2°C for 14 days. No significant changes of the active ingredient content were observed. The average concentrations of the active ingredient at Day 0, Day 1, Day 2, Day 7 and Day 14 were 98.41, 97.91, 98.20, 97.93, and 98.06%, respectively. These concentrations are all within the certified limits (lower limit: 95.65%, upper limit: 100.00%) listed on the proposed Basic CSF (dated 08/29/2018).

A 14-day accelerated corrosion characteristics study was conducted separately for 2,4-D Acid Technical (Batch No. 20150826) produced at the Basic Source (MRID 50631109). The test substance was stored in a polyethylene plastic bag (commercial packaging material) at 54 ± 2°C in the dark. Visual observations were made for the test substance and its packaging initially and after 14 days of storage. The results showed that no signs of corrosion (such as perforations or leaks) of the commercial packaging were observed during the course of the study. No change in the container weight and no physical changes of the test substance were noted.

DP BARCODE No.: D449902; **FILE SYMBOL/REG. No.:** 74468-12 (basic CSF & altCSF#1); **PRODUCT NAME:** 2,4-D Acid Technical; **DECISION No.:** 543943; **PC Code(s):** 030001; **ACTION CODE:** R351; **FOOD Use:** No; **REGISTRANT:** ProActive, LLC

A 14-day accelerated storage stability study for 2,4-D Acid Technical produced at the Alternate Source was performed at $54 \pm 2^{\circ}\text{C}$. The test substance was stored in a woven polyethylene plastic bag (commercial packaging material). The concentration of the active ingredient was determined initially and after 14 days of storage using the validated enforcement analytical method (Method No. 510G1080A-1). Also, the test substance was visually examined for any physical changes. The results showed that the product was clumping at the beginning and at the end of the 14-day storage. The average concentration of the active ingredient decreased from 96.984% at Day 0 to 88.790% at Day 14. The concentration of the active ingredient after 14 days of storage is not within the certified limits (lower limit: 95.65%, upper limit: 100.00%) listed on the proposed Basic CSF (dated 08/29/2018). This decline in the active ingredient content might be caused by the moisture absorbed during the storage.

A 14-day accelerated corrosion characteristics study was conducted concurrently with the storage stability study for 2,4-D Acid Technical produced at the Alternate Source. The results showed that no signs of corrosion (such as darkening, rust, perforations, pitting, etc.) of the commercial packaging material (woven polyethylene plastic) were observed during the 14-day storage stability study at $54 \pm 2^{\circ}\text{C}$.

CONCLUSIONS:

The CITAB has reviewed the proposed basic and alternate CSFs, and the supporting group A and group B data for 2,4-D Acid Technical and has concluded that:

1. The product chemistry data submitted for guidelines 830.1550 (product identity and composition), 830.1600 (description of materials used to produce the product), 830.1620 (description of production process), 830.1670 (discussion of the formation of impurities), 830.1700 (preliminary analysis), 830.1750 (certified limits), and 830.1800 (enforcement analytical method) are acceptable.
2. The five-batch preliminary analysis results show that the percent by weight of the active ingredient in the product from the Alternate Source ranged from 94.510% to 96.139%, with a mean of 95.753%, which is within the certified limits (lower limit: 95.65%, upper limit: 100.00%) listed on the proposed Basic CSF (dated 08/29/2018).
3. The proposed Basic CSF (dated 08/29/2018) and Alternate CSF (dated 08/29/2018) are acceptable. The alternate CSF is in compliance with 40CFR§152.43.
4. It is recommended that "Other Ingredients" (instead of "Related Ingredients") be used on the product label per PR Notice 97-6.
5. The group B (physical-chemical properties) data submitted for the both sites satisfy the data requirements of 40CFR§158.310(e)

DP BARCODE No.: D449902; **FILE SYMBOL/REG. No.:** 74468-12 (basic CSF & altCSF#1); **PRODUCT NAME:** 2,4-D Acid Technical; **DECISION No.:** 543943; **PC Code(s):** 030001; **ACTION CODE:** R351; **FOOD Use:** No; **REGISTRANT:** ProActive, LLC

830.1550. Product identity & composition: (MRID Nos. 50631101 and 50631102)

Common Name: 2,4-D Acid

IUPAC Name: 2,4-dichlorophenoxyacetic acid

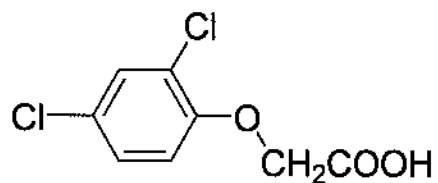
CAS Name: Not provided

CAS Number: 94-75-7

Molecular formula: $C_8H_5Cl_2O_3$

Molecular weight: 220.04 g/mol

Structural formula:



DP BARCODE No.: D449902; FILE SYMBOL/REG. No.: 74468-12 (basic CSF & altCSF#1); PRODUCT NAME: 2,4-D Acid Technical; DECISION No.: 543943; PC Code(s): 030001; ACTION CODE: R351; FOOD Use: No; REGISTRANT: ProActive, LLC
Group A Product Chemistry Data

Table 1. Manufacturing and Impurity Data for "2,4-D Acid Technical"				
GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and composition	50631101	A	Adequately described
830.1600	Description of materials used to produce the product	50631101	A	SDSs of the starting materials, and their suppliers and specifications were provided for both basic and alternate manufacturing sources.
830.1620	Description of production process	50631101	A	Detailed descriptions of the production processes for both basic and alternate manufacturing sites were provided.
830.1670	Discussion of formation of impurities	50631101	A	The identities and origins of potential impurities were provided for both basic and alternate manufacturing sites.
830.1700	Preliminary analysis	50631103, 50631104, 50631105	A	Five-batch analyses of the active ingredient and impurities were provided for both basic and alternate manufacturing sites.
830.1750	Certified limits	50631101	A	The certified limits for the active ingredient and upper certified limits for the impurities are within EPA's Standard Certified Limits for both basic and alternate manufacturing sources. Note that the upper certified limits for the two impurities [REDACTED] listed on the Alternate CSF, which are not the same as those reported on Page 17 in the confidential attachment of MRID 50631102, are out of their respective OCSPP-recommended ranges.
830.1800	Enforcement analytical method	50631103, 50631104, 50631105	A	The validated analytical method for quantifying the active ingredient at both basic and alternate manufacturing sites was HPLC-UV.
A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress; U = Up-grade (additional information required);				

DP BARCODE No.: D44996; FILE SYMBOL/REG. No.: 74468-12 (bas. SF & altCSF#1); **PRODUCT NAME:** 2,4-D Acid Technical; **DECISION No.:** 543943; **PC Code(s):** 030001; **ACTION CODE:** R351; **FOOD Use:** No; **REGISTRANT:** ProActive, LLC

830 Series Subgroup B (Physical-Chemical Properties)

Note that the relevant Group B product chemistry data for the Basic Source were included in MRIDs 50631106 through 50631117, while those for the Alternate Source were included in MRID 50631104.

Table 2: Physical and Chemical Properties for "2,4-D Acid Technical"				
GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	Color	50631106, 50631104	A	White color (Basic Source); Off-white or cream color (Alternate Source)
830.6303	Physical state	50631106, 50631104	A	Solid with crystalline appearance (Basic Source); Powder with clumping (Alternate Source)
830.6304	Odor	50631106, 50631104	A	Characteristic odor (Basic Source); Characteristic old rubber odor (Alternate Source)
830.6313 830.6317	Stability to normal and elevated temperatures, metals, and metal ions	50631107, 50631104	A	The product produced at the Basic Source was stable when it was stored at room temperature and at elevated temperature ($54 \pm 2^{\circ}\text{C}$) for 14 days. The product was found to be compatible with iron chips, aluminum shots, iron acetate, aluminum rods, and aluminum acetate at both temperatures. The product produced at the Alternate Source was stable when it was stored at room temperature and at elevated temperature ($54 \pm 2^{\circ}\text{C}$) for 14 days. The product was found to be compatible with iron filings, iron acetate, and aluminum acetate at both temperatures.
830.6314	Oxidation/reduction: chemical incompatibility	50631108, 50631104	A	The product produced at the Basic Source was found to be compatible with water, mono-ammonium phosphate, zinc powder, kerosene, and potassium permanganate. The product produced at the Alternate Source was found to be compatible with water, mono-ammonium phosphate, iron powder, and potassium permanganate.
830.6315	Flammability	Data Matrix (dated 08/20/2018)	NA	The product does not contain combustible liquids.
830.6316	Explosibility	Data Matrix (dated 08/20/2018)	NA	The product does not contain explosive components.

DP BARCODE No.: D44996 FILE SYMBOL/REG. No.: 74468-12 (bas. CSF & altCSF#1); PRODUCT NAME: 2,4-D Acid Technical; DECISION No.: 543943; PC Code(s): 030001; ACTION CODE: R351; FOOD Use: No; REGISTRANT: ProActive, LLC

Table 2: Physical and Chemical Properties for "2,4-D Acid Technical"

GLN	Requirement	MRID	Status	Result or Deficiency
830.6317	One Year storage stability	50631107, 50631104	A	<p>Basic Source: The product was stable when it was stored in a polyethylene plastic bag at $54 \pm 2^{\circ}\text{C}$ for 14 days.</p> <p>Alternate Source: The concentration of the active ingredient after 14 days of storage was 88.790% w/w, which is not within the certified limits listed on the proposed Basic CSF (dated 08/29/2018). This decrease (8.45%) in the active ingredient content might be caused by the moisture absorbed during the 14-day storage.</p>
830.6319	Miscibility		N/A	Not applicable, the product is a solid.
830.6320	One Year corrosion characteristics	50631109, 50631104	A	<p>Basic Source: No signs of corrosion (such as perforations or leaks) of the commercial packaging material (polyethylene plastic) were observed during the 14-day corrosion characteristics study at $54 \pm 2^{\circ}\text{C}$.</p> <p>Alternate Source: No signs of corrosion (such as darkening, rust, perforations, pitting, etc.) of the commercial packaging material (woven polyethylene plastic) were observed during the 14-day storage stability study at $54 \pm 2^{\circ}\text{C}$.</p>
830.7000	pH	50631110, 50631104	A	<p>2.95 at 19.7°C (1% w/v aqueous suspension) (Basic Source);</p> <p>2.73 at 18.8°C (1% w/v aqueous suspension) (Alternate Source)</p>

DP BARCODE No.: D44996 FILE SYMBOL/REG. No.: 74468-12 (bas. SF & altCSF#1); PRODUCT NAME: 2,4-D Acid Technical; DECISION No.: 543943; PC Code(s): 030001; ACTION CODE: R351; FOOD Use: No; REGISTRANT: ProActive, LLC

Table 2: Physical and Chemical Properties for "2,4-D Acid Technical"

GLN	Requirement	MRID	Status	Result or Deficiency		
830.7050	UV/Visible absorption	50631111, 50631104	A	The UV/Visible absorption results for the Basic Source are presented below.		
				Conditions	λ (nm)	ϵ (L/mol.cm) (Log ϵ)
				Neutral	230	9091 (3.96)
					284	1951 (3.29)
				Acidic	206	26395 (4.42)
					228	9230 (3.97)
					282	1758 (3.24)
				Basic	230	9102 (3.96)
					284	1952 (3.29)
				The UV/Visible absorption results for the Alternate Source are presented below.		
				Conditions	λ (nm)	ϵ (L/mol.cm)
				Neutral	200.55	34261
					229.15	7441
					283.10	1601
Acidic	228.60	8213				
	283.70	1944				
Basic	229.90	8159				
	283.30	1854				
830.7100	Viscosity		N/A	Not applicable, the product is a solid.		
830.7200	Melting point	50631112, 50631104	A	139.5 - 140.6°C (Basic Source); 138.1 - 139.6°C (Alternate Source)		

DP BARCODE No.: D4499; FILE SYMBOL/REG. No.: 74468-12 (bas. USF & altCSF#1); PRODUCT NAME: 2,4-D Acid Technical; DECISION No.: 543943; PC Code(s): 030001; ACTION CODE: R351; FOOD Use: No; REGISTRANT: ProActive, LLC

Table 2: Physical and Chemical Properties for "2,4-D Acid Technical"

GLN	Requirement	MRID	Status	Result or Deficiency
830.7220	Boiling point		N/A	Not applicable, the product is a solid.
830.7300	Density	50631113, 50631104	A	Relative density: 1.5791 g/mL at 19.98°C (Basic Source); Pour density: 0.578 g/mL at 20.0 ± 0.5°C, tap density: 0.743 g/mL at 20.0 ± 0.5°C (Alternate Source)
830.7370	Dissociation constants in water (DC)	50631114, 50631104	A	pKa = 3.30 (Basic Source); pKa = 3.008 (Alternate Source)
830.7550	Partition coefficient	50631115, 50631104	A	Log Pow = 2.563 at pH 1.41 and 20.3°C (Basic Source); Log Pow = 2.736 at pH 0.5 (Alternate Source)
830.7840	Water solubility	50631116, 50631104	A	0.3224 g/L at 20°C and pH 1.17 (Basic Source); 0.584 g/L at 20°C (pH unspecified) (Alternate Source)
830.7950	Vapor pressure	50631117, 50631104	A	1.09×10^{-2} mPa at 23°C, 1.73×10^{-2} mPa at 25°C and 5.32×10^{-2} mPa at 30°C (Basic Source); 1.29×10^{-4} Pa at 20°C, 1.82×10^{-4} Pa at 25°C, 3.76×10^{-4} Pa at 35°C, 5.31×10^{-4} Pa at 45°C and 1.00×10^{-3} Pa at 50°C (Alternate Source)

A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress; U = Up-grade (additional information required); W = waivers

DP BARCODE No.: D4499, FILE SYMBOL/REG. No.: 74468-12 (bas. JSF & altCSF#1); PRODUCT NAME: 2,4-D Acid Technical; DECISION No.: 543943; PC Code(s): 030001; ACTION CODE: R351; FOOD Use: No; REGISTRANT: ProActive, LLC

830.1800 (enforcement analytical method)
(MRID Nos. 50631103, 50631104 and 50631105)

The analytical method for quantifying the active ingredient in five representative batches of 2,4-D Acid Technical produced at the Basic Source was HPLC-UV at 230 nm with a DAD detector and external standard calibration, which was validated in terms of linearity, selectivity, accuracy (recovery), precision (repeatability), intermediate precision, LOD and LOQ (MRID 50631103). The identity of the active ingredient was confirmed by the retention time (HPLC-UV) and spectra (MS, UV, IR, and ¹H-NMR) obtained from the five batches of the test item and 2,4-D Acid analytical standard (MRID 50631103).

The impurities profile was determined using

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The registrant provided the following information for quantifying the active ingredient in 2,4-D Acid Technical produced at the Basic Source (MRID 50631103).

DP BARCODE No.: D44990, FILE SYMBOL/REG. No.: 74468-12 (bas. CSF & altCSF#1); PRODUCT NAME: 2,4-D Acid Technical; DECISION No.: 543943; PC Code(s): 030001; ACTION CODE: R351; FOOD Use: No; REGISTRANT: ProActive, LLC

5.2.4 Quantification of active ingredient

The quantification of the active ingredient was performed by a validated method (Appendix 1) using liquid chromatography coupled to UV detector. The concentrations of the active ingredient in each batch of the test substance were determined in duplicate by external calibration.

5.2.4.1 Reference substance information

Standard name	Code	Purity (%)	Physical state	Origin	Batch	Expiry date
2,4-D	B8129	98.3	Solid	Chem Service	2560800	30/Apr/2019

5.2.4.2 Equipment

Analytical balance;
Liquid chromatograph Agilent 1100 series;
Mechanical stirrer;
Micropipettes;
Sonicator;
All laboratory common glassware.

5.2.4.3 Reagents

Acetonitrile HPLC grade;
Formic acid PA grade;
Ultra Pure Water – Milli-Q system.

5.2.4.4 Preparation of calibration solutions

A stock solution of active ingredient was prepared by weighting of 11.25 mg of 2,4-D analytical standard in volumetric flask of 10 mL; the volume was completed with acetonitrile and the solution was stirred and sonicated until complete solubilization, producing the stock solution with 1105.88 mg.L⁻¹ of 2,4-D analytical standard.

This stock solution was diluted with acetonitrile according to the following table in order to produce the calibration solutions.

Calibration solutions	Aliquot of stock solution (µL)	Final Volume (µL)	Concentration of 2,4-D (mg.L ⁻¹)
Solution B	300	1000	331.76
Solution C	400	1000	442.35
Solution D	500	1000	552.94
Solution E	600	1000	663.53
Solution F	700	1000	774.12
Solution G	800	1000	884.70

DP BARCODE No.: D44996; FILE SYMBOL/REG. No.: 74468-12 (basic, SF & altCSF#1); PRODUCT NAME: 2,4-D Acid Technical; DECISION No.: 543943; PC Code(s): 030001; ACTION CODE: R351; FOOD Use: No; REGISTRANT: ProActive, LLC

5.2.4.5 Preparation of test substance solutions

Solutions from all five batches of the test substance were prepared in duplicate by weighing approximately 30 mg of sample in volumetric flask of 50.0 mL. The volumes were completed with acetonitrile and the solutions were sonicated until complete solubilization, producing the work solutions with approximately 600.00 mg.L⁻¹ (Table 2).

5.2.4.6 Instrument parameters

Equipment:	Liquid chromatograph Agilent 1100 series
Detector:	UV-DAD
Column:	Eclipse XDB C18 (150 mm x 4.6 mm x 5 µm)
Wavelength:	230 nm
Flow:	1.0 mL.min ⁻¹
Injection volume:	3.0 µL
Run time:	5 minutes
Oven temperature:	40°C
Mobile phase:	Acetonitrile / Water acidified with 0.1% (v/v) of formic acid (70:30 % v/v)

5.2.4.7 Calculation

- Active ingredient concentration (% w/w)

$$C = \frac{C_d}{C_{ts}} \times 100$$

Where: C = concentration of analyte in the sample (% w/w);

C_d = determined concentration of analyte in the solution (mg.L⁻¹);

C_{ts} = concentration of test substance in the solution (mg.L⁻¹).

The analytical method for quantifying the active ingredient in five representative batches of 2,4-D Acid Technical produced at the Alternate Source was HPLC-UV at 229 nm (Method No. 510G1080A-1), which was validated for linearity, precision and accuracy (MRID 50631104). The identity of the active ingredient was confirmed using HPLC-UV/PDA, ES-MS, ¹³C-NMR and ¹H-NMR spectra analysis against 2,4-D Acid analytical standard.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

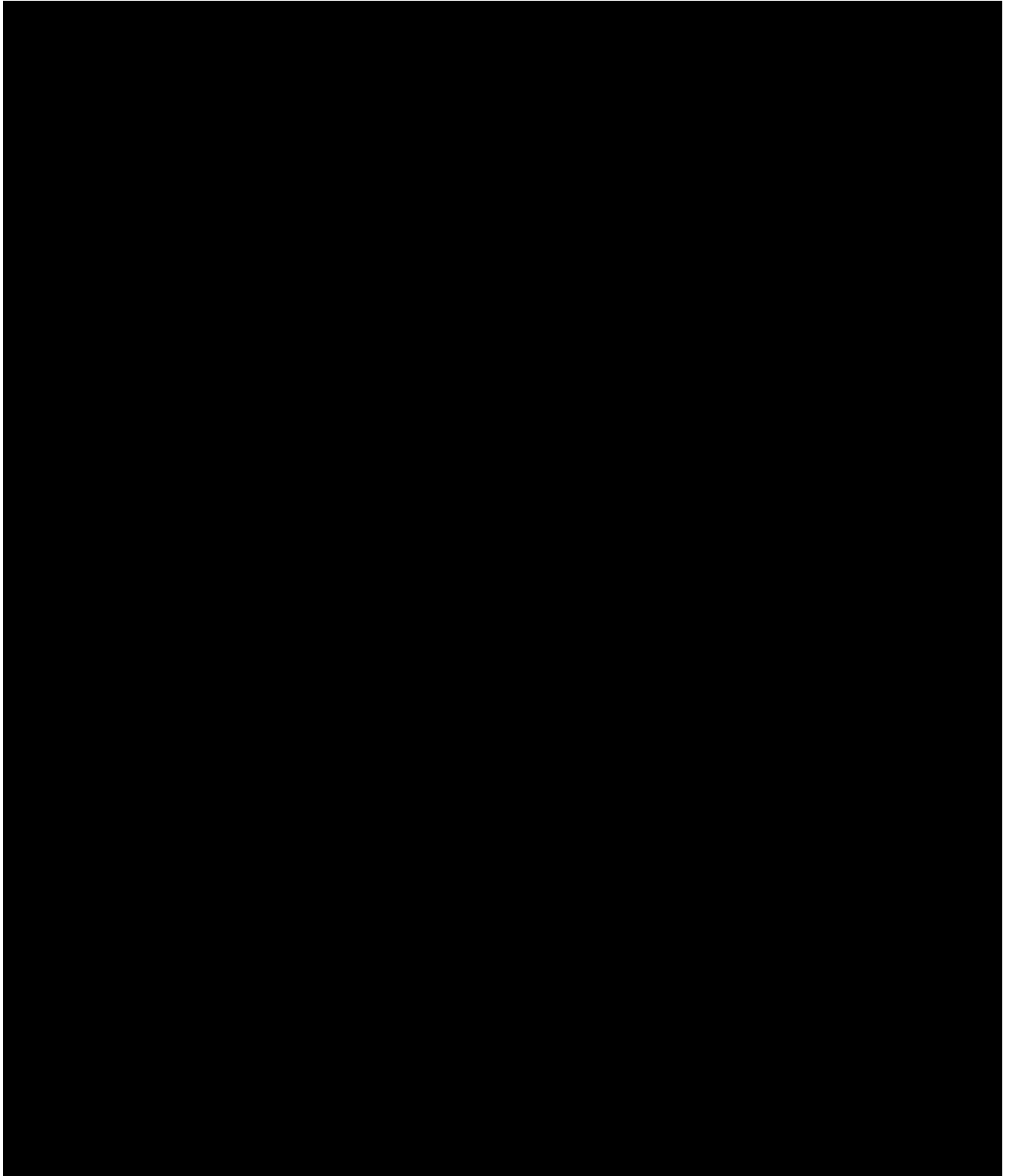
[REDACTED]

The registrant provided the following information for quantifying the active ingredient in 2,4-D Acid Technical produced at the Alternate Source (MRID 50631104). Details of the methods can be seen under the MRID's indicated.

DP BARCODE No.: D44990; FILE SYMBOL/REG. No.: 74468-12 (basic CSF & altCSF#1); PRODUCT NAME: 2,4-D Acid Technical; DECISION No.: 543943; PC Code(s): 030001; ACTION CODE: R351; FOOD Use: No; REGISTRANT: ProActive, LLC

CONFIDENTIAL APPENDIX

830.1600 (description of materials used to produce the product)
(MRID Nos. 50631101 and 50631102)



Manufacturing process information may be entitled to confidential treatment

DP BARCODE No.: D44996; **FILE SYMBOL/REG. No.:** 74468-12 (basic CSF & altCSF#1); **PRODUCT NAME:** 2,4-D Acid Technical; **DECISION No.:** 543943; **PC Code(s):** 030001; **ACTION CODE:** R351; **FOOD Use:** No; **REGISTRANT:** ProActive, LLC

CONFIDENTIAL APPENDIX

830,1750: Certified limits
(MRID Nos. 50631101 and 50631102)

The nominal concentrations of the active ingredient and impurities on the proposed Basic CSF and Alternate CSF are the same as their respective averages derived from the five-batch preliminary analyses of 2,4-D Acid Technical produced at both basic and alternate manufacturing sites (MRIDs 50631103 through 50631105).

The certified limits for the active ingredient and upper certified limits for the impurities provided on the Basic CSF are consistent with those reported on Page 18 in the confidential attachment of MRID 50631101, and also are within their respective OCSPP-recommended ranges. The proposed certified limits for the impurities listed on the Alternate CSF are based on the standard certified limits. The certified limits for the other ingredients listed on the Alternate CSF are within EPA standard certified limits.

Copies of the proposed Basic CSF (dated 08/29/2018) and Alternate CSF (dated 08/29/2018) are shown below.

DP BARCODE No.: D44990, FILE SYMBOL/REG. No.: 74468-12 (basic CSF & altCSF#1); PRODUCT NAME: 2,4-D Acid Technical; DECISION No.: 543943; PC Code(s): 030001; ACTION CODE: R351; FOOD Use: No; REGISTRANT: ProActive, LLC

DATA EVALUATION RECORD

2,4-D ACID TECHNICAL

STUDY TYPE: PRODUCT CHEMISTRY REVIEW

OCSP 830.1550; 830.1600; 830.1620; 830.1670; 830.1700; 830.1750; 830.1800; 830.6302; 830.6303; 830.6304; 830.6313; 830.6314; 830.6315; 830.6316; 830.6317; 830.6319; 830.6320; 830.7000; 830.7050; 830.7100; 830.7200; 830.7220; 830.7300; 830.7370; 830.7550; 830.7840; 830.7950

MRIDS 50631101, 50631102, 50631103, 50631104, 50631105, 50631106, 50631107, 50631108, 50631109, 50631110, 50631111, 50631112, 50631113, 50631114, 50631115, 50631116, 50631117

Prepared for
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Summitec Corporation
9724 Kingston Pike, Suite 503
Knoxville, Tennessee

Task Order No. Active 1-121

Primary Reviewer:
Maolian Chen, Ph.D.

Signature: Maolian Chen
Date: 05/30/2019

Secondary Reviewers:
Thomas C. Marshall, Ph.D., DABT (1981-2016)

Signature: Thomas C. Marshall
Date: 05/30/2019

Robert H. Ross, M.S., Project Manager

Signature: Robert H. Ross
Date: 05/30/2019

Quality Assurance:
Angela M. Edmonds, B.S.

Signature: Angela M. Edmonds
Date: 05/30/2019

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.
Summitec Corp. for the U.S. Environmental Protection Agency under Contract No. EP-W-16-019

Adeeb, Shanta

From: Jane Miller <jmiller@biologicconsulting.com>
Sent: Tuesday, May 28, 2019 11:08 AM
To: Adeeb, Shanta
Cc: Ondish, Mindy
Subject: RE: PRIA Due Date Renegotiation - PRIA Amendment for EPA Reg. No. 74468-12

Dear Shanta,

PRIA Due Date Renegotiation for:

EPA Reg. No. 74468-12
Decision No. 543943
Current PRIA date: May 28, 2019
New PRIA Date July 26, 2019

Thank you for your email. We appreciate the difficulty the Agency is facing with the backlog of work. ProActive will accept the 60 day PRIA due date extension however we do have reservations since you have not heard anything back from the product chemistry group. The 2,4-D registration is very important to ProActive and due to the trade issues with China, ProActive needs to have the new CSF's approved in order to meet the selling season which starts in August.

We hope that this extension is all that is needed to get the amendment approved. ProActive is a small business and not being able to meet the sale season will cause a serious financial hardship.

Regards,

Jane M. Miller

BIOLOGIC REGULATORY CONSULTING, INC.
10529 Heritage Bay Blvd.
Naples, FL 34120
Tel: 239-331-3422
Cell: 239-238-6584

From: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Sent: Tuesday, May 28, 2019 7:25 AM
To: Jane Miller <jmiller@biologicconsulting.com>
Cc: Ondish, Mindy <ondish.mindy@epa.gov>
Subject: RE: Status Update for EPA Reg. No. Status of PRIA Amendment for EPA Reg. No. 74468-12
Importance: High

Good Morning Jane,

I have not heard back from the science team so I am recommending a 60 day renegotiation which would make the new PRIA date July 26, 2019. If you agree to this new PRIA date please send a renegotiation with the following information:

EPA Reg. No. 74468-12
Decision No. 543943
Current PRIA date: May 28, 2019
New PRIA Date July 26, 2019

Thanks for working with the agency during this time.

Best Regards,

Shanta

From: Jane Miller <jmiller@biologicconsulting.com>
Sent: Friday, May 24, 2019 9:20 AM
To: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Status Update for EPA Reg. No. Status of PRIA Amendment for EPA Reg. No. 74468-12

Hi Shanta,

Have you heard anything back from product chemistry on this pending application?

Regards,

Jane M. Miller

BIOLOGIC REGULATORY CONSULTING, INC.
10529 Heritage Bay Blvd.
Naples, FL 34120
Tel: 239-331-3422
Cell: 239-238-6584

From: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Sent: Thursday, May 16, 2019 2:54 PM
To: Jane Miller <jmiller@biologicconsulting.com>
Subject: Status Update for EPA Reg. No. Status of PRIA Amendment for EPA Reg. No. 74468-12

Good Afternoon Ms. Miller,

I just wanted you to know that the product chemistry review for this action is *still pending* at this time. I have reached out to the product chemistry team to see if they will have the review completed by the May 28, 2019 PRIA date. Once I hear back from the team I will let you know if we are still on track to meet the current PRIA date.

Regards,

Shanta Adeeb, M.S.
Risk Manager, Herbicide Branch
Registration Division, Office of Pesticide Programs
United States Environmental Protection Agency
Number: 703-347-0502, Email: adeeb.shanta@epa.gov



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 12, 2018

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

BIOLOGIC REGULATORY CONSULTING, INC.
PROACTIVE, LLC
10529 HERITAGE BAY BLVD.
NAPLES, FL 34120

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 31-AUG-18. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

BIOLOGIC REGULATORY CONSULTING, INC.
agribusiness professionals

August 29, 2018

MRID No. 50631100

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Room S-4900, 4th Floor
Arlington, VA 22202

ATTN: Mr. Grant Rowland (PM #23)

RE: Application for Pesticide Amendment
"2,4-D Technical", EPA Reg. No. 74468-12

Dear Mr. Rowland:

On behalf of ProActive, LLC we are submitting this Application for Pesticide Amendment for the above-mentioned product. This amendment action is to: 1) amend to a full end use registration, and 2) add unregistered AI sources to the confidential statement of formula. The proposed amended formulation and revised label are similar to "Nufarm 2,4-D Technical Acid", EPA Reg. No. 35935-7.

The following documents are submitted for this amendment action:

Administrative Materials:

- Application for Pesticide Amendment (EPA Form 8570-1)
- Certification with Respect to Citation of Data (EPA Form 8570-34)
- Data Matrix (EPA Form 8570-35)
- Confidential Statement of Formula – Basic and Alternate (EPA Form 8570-4)
- Draft revised labeling

Data Submitted:

GUIDELINE NOS.	STUDY TITLE	MRID NUMBER
830.1500, 830.1600, 830.1620, 830.1670, 830.1750	Product Identity and Composition of 2,4-D Acid TGA1	50631101
830.1500, 830.1600, 830.1620, 830.1670, 830.1750	Product Identity and Composition of 2,4-D Acid TGA1	50631102
830.1700, 830.1800, 830.7050	Preliminary Analysis, Enforcement Analytical Method & Qualitative and Quantitative Profile of the Test Substance 2,4-D Technical (Five Batch Assay)	50631103
830.1700, 830.1750, 830.1800, 830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6317, 830.6320, 830.7000, 830.7050, 830.7200, 830.7300, 830.7370, 830.7550, 830.7840, 830.7950	Determination of the Physical and Chemical Characteristics and Preliminary Analysis of Technical 2,4-Dichlorophenoxyacetic Acid (2,4-D)	50631104
830.1700, 830.1800	Polychlorinated Dibenzodioxins and Polychlorinated Dibenzofurans Analysis of 2,4-D TGA1	50631105

10529 Heritage Bay Blvd.
Naples, FL 34120
Tel: 239-331-3422
Email: jmiller@biologicconsulting.com

2,4-D Acid Technical, EPA Reg. No. 74468-12
Amendment – 08 29 2018

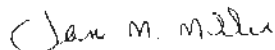
830.6302, 830.6303, 830.6304	Physical State, Appearance, Color, and Odor of 2,4-D Technical	50531106
830.6313	Stability to Normal and Elevated Temperatures, Metal and Metal Ions of 2,4-D Technical	50631107
830.6314	Oxidation/Reduction: Chemical Incompatibility of 2,4-D Technical	50631108
830.6320	Reactivity with the Container Material of 2,4-D Technical	50631109
830.7000	Determination of the pH Value of Aqueous Solution of 2,4-D Technical	50631110
830.7050	UV-VIS Adsorption Spectra of 2,4-D Technical	50631111
830.7200	Melting Point and Range of 2,4-D Technical	50631112
830.7300	Determination of the Relative Density of 2,4-D Technical	50631113
830.7370	Dissociation Constant in Water of 2,4-D Technical	50631114
830.7550	Partition Coefficient (N-octanol/water) of 2,4-D Technical	50631115
830.7840	Solubility in Water and Organic Solvents (n-hexane and ethyl acetate) of 2,4-D Technical	50631116
830.7950	Vapor Pressure of 2,4-D Technical	50631117
875.2900	Evaluation of Predictive Algorithms Use for Estimating Potential Postapplication, Nondietary Ingestion Exposures to Pesticides Associated with Children's Hand-To-Mouth Behavior	50631118

To satisfy additional data requirements for this amendment action, ProActive, LLC has chosen the selective method of data support and has included the appropriate citations on the enclosed Data Matrix. ProActive has sent offer to pay letters to the companies listed on the enclosed Data Matrix.

This application for amendment will fall within the category on Table 5 - Registration Division: Amendments, EPA No. R351; CR No. 57. The PRIA fee for this application is \$13,226.

Should you have any questions, or wish to reach me, please feel free to contact our office at 239-331-3422.

Sincerely,



Jane M. Miller
Agent to ProActive, LLC

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 8/31/18

Experts In-Processing Signature: NA Date 9/7/18

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>74468-12</u>		EPA Receipt Date: <u>8/31/18</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
	<u>No inerts to review.</u>					
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

Documentation: Pass

All required forms are complete.

Inerts: N/A

Technical and impurities only, no inerts to review.

113: Pass

med 502311

Status: Pass

MS 09/12/18

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 6, 2018

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-543943
EPA File Symbol or Registration Number: 74468-12
Product Name: 2,4-D ACID TECHNICAL
EPA Receipt Date: 31-Aug-2018
EPA Company Number: 74468
Company Name: PROACTIVE, LLC

JANE MILLER
BIOLOGIC REGULATORY CONSULTING, INC.
PROACTIVE, LLC
10529 HERITAGE BAY BLVD.
NAPLES, FL 34120-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R351

AMENDMENT;UNREGISTERED SOURCE OF ACTIVE INGREDIENT;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 347-0510.

Sincerely,

A handwritten signature in black ink, appearing to be "JEC", written over a horizontal line.

Front End Processing Staff
Information Technology & Resources Management Division

BIOLOGIC REGULATORY CONSULTING, INC.
agribusiness professionals

August 29, 2018

MRID No. 50631100

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Room S-4900, 4th Floor
Arlington, VA 22202

ATTN: Mr. Grant Rowland (PM #23)

RE: Application for Pesticide Amendment
"2,4-D Technical", EPA Reg. No. 74468-12

Dear Mr. Rowland:

On behalf of ProActive, LLC we are submitting this Application for Pesticide Amendment for the above-mentioned product. This amendment action is to: 1) amend to a full end use registration, and 2) add unregistered AI sources to the confidential statement of formula. The proposed amended formulation and revised label are similar to "Nufarm 2,4-D Technical Acid", EPA Reg. No. 35935-7.

The following documents are submitted for this amendment action:

Administrative Materials:

- Application for Pesticide Amendment (EPA Form 8570-1)
- Certification with Respect to Citation of Data (EPA Form 8570-34)
- Data Matrix (EPA Form 8570-35)
- Confidential Statement of Formula – Basic and Alternate (EPA Form 8570-4)
- Draft revised labeling

Data Submitted:

GUIDELINE NOS.	STUDY TITLE	MRID NUMBER
830.1500, 830.1600, 830.1620, 830.1670, 830.1750	Product Identity and Composition of 2,4-D Acid TGA1	50631101
830.1500, 830.1600, 830.1620, 830.1670, 830.1750	Product Identity and Composition of 2,4-D Acid TGA1	50631102
830.1700, 830.1800, 830.7050	Preliminary Analysis, Enforcement Analytical Method & Qualitative and Quantitative Profile of the Test Substance 2,4-D Technical (Five Batch Assay)	50631103
830.1700, 830.1750, 830.1800, 830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6317, 830.6320, 830.7000, 830.7050, 830.7200, 830.7300, 830.7370, 830.7550, 830.7840, 830.7950	Determination of the Physical and Chemical Characteristics and Preliminary Analysis of Technical 2,4-Dichlorophenoxyacetic Acid (2,4-D)	50631104
830.1700, 830.1800	Polychlorinated Dibenzodioxins and Polychlorinated Dibenzofurans Analysis of 2,4-D TGA1	50631105

10529 Heritage Bay Blvd.
Naples, FL 34120
Tel: 239-331-3422
Email: jmiller@biologicconsulting.com

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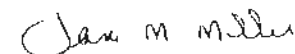
830.6302, 830.6303, 830.6304	Physical State, Appearance, Color, and Odor of 2,4-D Technical	50531106
830.6313	Stability to Normal and Elevated Temperatures. Metal and Metal Ions of 2,4-D Technical	50631107
830.6314	Oxidation/Reduction: Chemical Incompatibility of 2,4-D Technical	50631108
830.6320	Reactivity with the Container Material of 2,4-D Technical	50631109
830.7000	Determination of the pH Value of Aqueous Solution of 2,4-D Technical	50631110
830.7050	UV-VIS Adsorption Spectra of 2,4-D Technical	50631111
830.7200	Melting Point and Range of 2,4-D Technical	50631112
830.7300	Determination of the Relative Density of 2,4-D Technical	50631113
830.7370	Dissociation Constant in Water of 2,4-D Technical	50631114
830.7550	Partition Coefficient (N-octanol/water) of 2,4-D Technical	50631115
830.7840	Solubility in Water and Organic Solvents (n-hexane and ethyl acetate) of 2,4-D Technical	50631116
830.7950	Vapor Pressure of 2,4-D Technical	50631117
875.2900	Evaluation of Predictive Algorithms Use for Estimating Potential Postapplication, Nondietary Ingestion Exposures to Pesticides Associated with Children's Hand-To-Mouth Behavior	50631118

To satisfy additional data requirements for this amendment action, ProActive, LLC has chosen the selective method of data support and has included the appropriate citations on the enclosed Data Matrix. ProActive has sent offer to pay letters to the companies listed on the enclosed Data Matrix.



This application for amendment will fall within the category on Table 5 - Registration Division: Amendments. EPA No. R351: CR No. 57. The PRIA fee for this application is \$13,226.

Should you have any questions, or wish to reach me, please feel free to contact our office at 239-331-3422.

Sincerely,



Jane M. Miller
Agent to ProActive, LLC

 United States Environmental Protection Agency 1200 Pennsylvania Avenue, N.W. Washington, DC 20460-0001		<input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide – Section I			
1. Company/Product Number 74468-12		2. EPA Product Manager G. Rowland	
4. Company/ Product (Name) 2,4-D Acid Technical		3. Proposed Classification X None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) ProActive, LLC 10529 Heritage Bay Blvd. Naples, FL 34120 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i) my product is similar or identical in composition and labeling to: EPA Reg. No. 35935-7 Product Name Nufarm 2,4-D Technical Acid	
Section – II			
<input checked="" type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification – Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other – Explain below.	
Explanation: Use additional page(s) if necessary. (For Section I and Section II.) This is an amendment which will fall within the category on Table 5 - Registration Division: Amendments. This product is further defined under EPA No. 351; CR No. 57. This product is a "Re-Pack". The PRIA fee for this application is \$13,226. Jane Miller email: jmiller@biologicconsulting.com			
Section – III			
1. Material This Product Will Be Packaged In:			
Child Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify):
*Certification must be submitted		If "Yes" Unit Packaging Wt. No. Per Container	If "Yes" Packaging Wt. No. Per Container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	
		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling Accompanying Product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Stenciled <input type="checkbox"/> Paper glued <input type="checkbox"/> Other	
Section – IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application).			
Name Jane M. Miller		Title Agent	Telephone No. (Include Area Code) 239-238-6584
Certification			6. Date Application Received (Stamped)
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			
2. Signature 		3. Title Agent	
4. Typed Name Jane M. Miller		5. Date 08/29/2018	

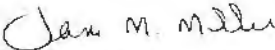
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401 M Street, S.W.

WASHINGTON, D.C. 20460

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DATA MATRIX

Date August 20, 2018		EPA Reg. No./File Symbol 74468-12		Page 1 of 15	
Applicant's/Registrant's Name & Address		Product:			
ProActive LLC 10529 Heritage Bay Blvd. Naples, FL 34120		2,4-D Acid Technical			
Ingredient 2,4-D					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition	50631101 and 50631102	ProActive LLC	OWN	
830.1600	Description of Materials Used to Produce the Product	50631101 and 50631102	ProActive LLC	OWN	
830.1620	Description of Production Process	50631101 and 50631102	ProActive LLC	OWN	
830.1650	Description of Formulation Process				1
830.1670	Discussion of Formation of Impurities	50631101 and 50631102	ProActive LLC	OWN	
830.1700	Preliminary Analysis	50631103, 50631104 and 50631105	ProActive LLC	OWN	
830.1750	Certified Limits	50631101 and 50631102	ProActive LLC	OWN	
830.1800	Enforcement Analytical Method	50631103, 50631104 and 50631105	ProActive LLC	OWN	
830.1900	Submittal of Samples				2
830.6302	Color	50631106 and 50631104	ProActive LLC	OWN	
830.6303	Physical State	50631106 and 50631104	ProActive LLC	OWN	
830.6304	Odor	50631106 and 50631104	ProActive LLC	OWN	
830.6313	Stability to normal & elevated temp., metal, metal ion	50631107 and 50631104	ProActive LLC	OWN	
830.6314	Oxidation/Reduction	50631108 and 50631104	ProActive LLC	OWN	
830.6315	Flammability / Flame Extension				3
830.6316	Explosibility				4
830.6317	Storage Stability	50631104	ProActive, LLC	OWN	
Signature 			Name and Title Jane M. Miller, Agent		Date 08/20/2018

Based on EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

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DATA MATRIX

Date August 20, 2018		EPA Reg. No./File Symbol 74468-12		Page 1 of 15	
Applicant's/Registrant's Name & Address		Product:			
ProActive LLC 10529 Heritage Bay Blvd. Naples, FL 34120		2,4-D Acid Technical			
Ingredient 2,4-D					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			ProActive LLC	OWN	
			ProActive LLC	OWN	
			ProActive LLC	OWN	
					1
			ProActive LLC	OWN	
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			ProActive LLC	OWN	
			ProActive LLC	OWN	
			ProActive LLC	OWN	
			ProActive LLC	OWN	
					3
					4
			ProActive, LLC	OWN	
Signature 			Name and Title Jane M. Miller, Agent		Date 08/20/2018

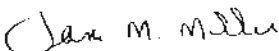
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DATA MATRIX

Date August 20, 2018		EPA Reg. No./File Symbol 74468-12		Page 2 of 15	
Applicant's/Registrant's Name & Address		Product			
ProActive LLC 10529 Heritage Bay Blvd. Naples, FL 34120		2,4-D Acid Technical			
Ingredient 2,4-D					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6319	Miscibility				5
830.6320	Corrosion Characteristics	50631109 and 50631104	ProActive LLC	OWN	
830.6321	Dielectric Breakdown Voltage				6
830.7000	pH	50631110 and 50631104	ProActive LLC	OWN	
830.7050	UV/Visible Spectrum	50631111 and 50631104	ProActive LLC	OWN	
830.7100	Viscosity				7
830.7200	Melting Point/ Melting Range	50631112 and 50631104	ProActive LLC	OWN	
830.7300	Density	50631113 and 50631104	ProActive LLC	OWN	
830.7370	Dissociation Constant	50631114 and 50631104	ProActive LLC	OWN	
830.7550	Partition Coefficient	50631115 and 50631104	ProActive LLC	OWN	
830.7840	Water Solubility	50631116 and 50631104	ProActive LLC	OWN	
830.7950	Vapor Pressure	50631117 and 50631104	ProActive LLC	OWN	
Signature 			Name and Title Jane M. Miller, Agent		Date 08/20/2018

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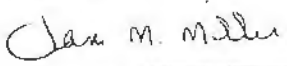
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DATA MATRIX

Date August 20, 2018		EPA Reg. No./File Symbol 74468-12		Page 2 of 15	
Applicant's/Registrant's Name & Address		Product			
ProActive LLC 10529 Heritage Bay Blvd. Naples, FL 34120		2,4-D Acid Technical			
Ingredient 2,4-D					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			ProActive LLC	OWN	5
			ProActive LLC	OWN	6
			ProActive LLC	OWN	
			ProActive LLC	OWN	
			ProActive LLC	OWN	7
			ProActive LLC	OWN	
			ProActive LLC	OWN	
			ProActive LLC	OWN	
			ProActive LLC	OWN	
			ProActive LLC	OWN	
Signature 			Name and Title Jane M. Miller, Agent		Date 08/20/2018

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Applicant's/Registrant's Name & Address ProActive LLC 10529 Heritage Bay Blvd. Naples, FL 34120		Product 2,4-D Acid Technical			
Ingredient 2,4-D					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.1110	Activated Sludge Sorption Isotherm	Cite-All		OLD	
835.1210	Soil Thin Layer Chromatography	Cite-All		OLD	
835.1220	Sediment and Soil Adsorption/Desorption Isotherm	Cite-All		OLD	
835.1230	Soil Adsorption/Desorption (Batch Equilibrium)	Cite-All		OLD	
835.1240	Leaching Studies	Cite-All		OLD	
835.1410	Laboratory Volatility	Cite-All		OLD	
835.2120	Hydrolysis as a Function of pH and Temperature	Cite-All		OLD	
835.2210	Direct Photolysis Rate in Water by Sunlight	Cited-All		OLD	
835.2240	Photodegradation in Water	Cite-All		OLD	
835.2310	Maximum Direct Photolysis Rate in Air from UV/Visible Spectroscopy	Cite-All		OLD	
835.2370	Photodegradation in Air	Cite-All		OLD	
835.2410	Photodegradation on Soil	Cite-All		OLD	
835.3100	Aerobic Aquatic Biodegradation	Cite-All		OLD	
835.3110	Ready Biodegradability	Cite-All		OLD	
835.3140	Ready Biodegradability – CO ₂ in Sealed Vessels (Headspace Test)	Cite-All		OLD	
835.3160	Biodegradability in Sea Water	Cite-All		OLD	
835.3170	Shake Flask Die-Away Test	Cite-All		OLD	
835.3180	Sediment/Water Microcosm Biodegradation Test	Cite-All		OLD	
Jane M. Miller		Jane M. Miller, Agent		08/20/2018	

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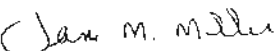
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ProActive LLC 10529 Heritage Bay Blvd. Naples, FL 34120		2,4-D Acid Technical			
Ingredient 2,4-D					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.3190	Aerobic Mineralization in Surface Water – Simulation Biodegradation test	Cite-All		OLD	
835.3200	Zahn-Wellens/EMPA Test	Cite-All		OLD	
835.3210	Modified SCAS Test	Cite-All		OLD	
835.3215	Inherent Biodegradability – Concawe Test	Cite-All		OLD	
835.3220	Porous Pot Test	Cite-All		OLD	
835.3240	Simulation Test – Aerobic Sewage Treatment: A. Activated Sludge Units	Cite-All		OLD	
835.3260	Simulation Test – Aerobic Sewage Treatment: B. Biofilms	Cite-All		OLD	
835.3280	Simulation Tests to Assess the Primary and Ultimate Biodegradability of Chemical Discharged to Wastewater	Cite-All		OLD	
835.3300	Soil Biodegradation	Cite-All		OLD	
35.3400	Anaerobic Biodegradability of Organic Chemicals	Cite-All		OLD	
835.3420	Anaerobic Biodegradability of Organic Compounds in Digested Sludge by Measurements of Gas Production	Cite-All		OLD	
835.4100	Aerobic Soil Metabolism	Cite-All		OLD	
835.4200	Anaerobic Soil Metabolism	Cite-All		OLD	
835.4300	Aerobic Aquatic Metabolism	Cite-All		OLD	
835.4400	Anaerobic Aquatic Metabolism	Cite-All		OLD	
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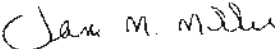
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Ingredient 2,4-D					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.5045	Modified SCAS Test for Insoluble and Volatile Chemicals	Cite-All		OLD	
835.5154	Anaerobic Biodegradation in the Subsurface	Cite-All		OLD	
835.5270	Indirect Photolysis Screening Test: Sunlight Photolysis in Waters Containing Dissolved Humic Substances	Cite-All		OLD	
835.6100	Terrestrial Field Dissipation	Cite-All		OLD	
835.6200	Aquatic (Sediment) Dissipation	46424401 46424402 46424403	Industry Task Force II on 2,4-D Research Data	PAY	
835.6300	Forestry Dissipation	Cite-All		OLD	
835.6400	Combination and Tank Mixes Field Dissipation	Cite-All		OLD	
835.7100	Ground Water Monitoring	47163505	2,4-DP-P Task Force	PAY	
835.8100	Volatility - Field	48862902	Dow AgroSciences	PAY	
850.1010	Acute Toxicity Freshwater Invertebrates	Cite-All		OLD	
850.1010	Gammarid Amphipod Acute Toxicity	Cite-All		OLD	
850.1025	Oyster Acute Toxicity (Shell Deposition)	Cite-All		OLD	
835.5045	Modified SCAS Test for Insoluble and Volatile Chemicals	Cite-All		OLD	
835.5154	Anaerobic Biodegradation in the Subsurface	Cite-All		OLD	
835.5270	Indirect Photolysis Screening Test: Sunlight Photolysis in Waters Containing Dissolved Humic Substances	Cite-All		OLD	
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ProActive LLC 10529 Heritage Bay Blvd. Naples, FL 34120		2,4-D Acid Technical			
Ingredient 2,4-D					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
				OLD	
				OLD	
				OLD	
				OLD	
				PAY	
				OLD	
				OLD	
			2,4-DP-P Task Force	PAY	
			Dow AgroSciences	PAY	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
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Ingredient 2,4-D

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.6100	Terrestrial Field Dissipation	Cite-All		OLD	
835.6200	Aquatic (Sediment) Dissipation	46424401 46424402 46424403	Industry Task Force II on 2,4-D Research Data	PAY	
835.6300	Forestry Dissipation	Cite-All		OLD	
835.6400	Combination and Tank Mixes Field Dissipation	Cite-All		OLD	
835.7100	Ground Water Monitoring	Cite-All		OLD	
835.8100	Volatility - Field	Cite-All		OLD	
840.1100	Spray Droplet Size Spectrum	Cite-All		OLD	
840.1200	Spray Field Deposition	Cite-All		OLD	
850.1010	Acute Toxicity Freshwater Invertebrates	Cite-All		OLD	
850.1010	Gammarid Amphipod Acute Toxicity	Cite-All		OLD	
850.1025	Oyster Acute Toxicity (Shell Deposition)	Cite-All		OLD	
50.1035	Mysid Acute Toxicity	Cite-All		OLD	
850.1045	Penaeid Acute Toxicity	Cite-All		OLD	
850.1055	Bivalve Acute Toxicity (Embryo-Larval)	Cite-All		OLD	
850.1075	Fish Acute Toxicity (Freshwater)	48939504 48892401	Industry Task Force II on 2,4-D Research Data Dow AgroSciences	PAY	
850.1075	Fish Acute Toxicity (Marine)	Cite-All		OLD	
850.1300	Daphnid Chronic Toxicity	Cite-All		OLD	
850.1350	Mysid Chronic Toxicity				8
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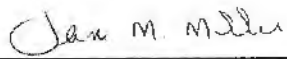
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ProActive LLC 10529 Heritage Bay Blvd. Naples, FL 34120

Product

2,4-D Acid Technical

Ingredient 2,4-D

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
				OLD	
			Industry Task Force II on 2,4-D Research Data	PAY	
				OLD	
				OLD	
				OLD	
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				OLD	
				OLD	
			Industry Task Force II on 2,4-D Research Data Dow AgroSciences	PAY	
				OLD	
				OLD	
					8
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Ingredient 2,4-D

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.1400	Fish Early-Life Stage (Freshwater)	Cite-All		OLD	
850.1400	Fish Early-Life Stage (Saltwater)	Cite-All		OLD	
850.1500	Fish Life-Cycle	Cite-All		OLD	
850.1710	Oyster Bioconcentration Factor				9
850.1730	Fish Bioconcentration Factor				9
850.1735	Whole Sediment Acute Toxicity Invertebrates (Freshwater)	Cite-All		OLD	
850.1740	Whole Sediment Acute Toxicity Invertebrates (Marine)	Cite-All		OLD	
850.2100	Acute Avian Toxicity	Cite-All		OLD	
850.2200	Avian Dietary Toxicity	49472501	Industry Task Force II on 2,4-D Research Data	PAY	
850.2300	Avian Reproduction	Cite-All		OLD	
850.2400	Wild Mammal Toxicity	Cite-All		OLD	
850.2500	Simulated or Actual Field Testing	Cite-All		OLD	
850.3020	Honeybee Acute Contact Toxicity	50181701	Industry Task Force II on 2,4-D Research Data	PAY	
850.3030	Honeybee Toxicity of Residues on Foliage	Cite-All			10
850.3040	Field Testing for Pollinators	Cite-All			10
850.3100	Earthworm Subchronic Toxicity	Cite-All		OLD	
850.3200	Soil Microbial Community Toxicity Test	Cite-All		OLD	
850.3300	Modified Activate Sludge, Respiration Inhibition Test	Cite-All		OLD	

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Ingredient 2,4-D		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
				OLD	
				OLD	
				OLD	
					9
					9
				OLD	
				OLD	
				OLD	
			Industry Task Force II on 2,4-D Research Data	PAY	
				OLD	
				OLD	
				OLD	
			Industry Task Force II on 2,4-D Research Data	PAY	
					10
					10
				OLD	
				OLD	
				OLD	

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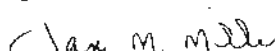
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Applicant's/Registrant's Name & Address	ProActive LLC 10529 Heritage Bay Blvd. Naples, FL 34120				
Product	2,4-D Acid Technical				
Ingredient	2,4-D				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.4100	Seedling Emergence	47106001	Industry Task Force II on 2,4-D Research Data	PAY	
850.4150	Vegetative Vigor	47106002 47106004	Industry Task Force II on 2,4-D Research Data	PAY	
850.4230	Early Seedling Growth Toxicity	47106003	Industry Task Force II on 2,4-D Research Data	PAY	
850.4300	Terrestrial Plants Field Study	Cite-All		OLD	
850.4400	Aquatic Plant Growth Toxicity Test Using <i>Lemna</i> spp	Cite-All		OLD	
850.4450	Aquatic Plants Field Study	Cite-All		OLD	
850.4500	Algal Toxicity	Cite-All		OLD	
850.4550	Cyanobacteria (<i>Anabaena flos-aquae</i>) Toxicity	Cite-All		OLD	
850.4600	Rhizobium-Legume Toxicity	Cite-All		OLD	
850.4800	Plant Uptake and Translocation Test	Cite-All		OLD	
850.4900	Terrestrial Soil-Core Microcosm Test	Cite-All		OLD	
850.6100	Environmental Chemistry Methods and Associated Independent Laboratory Validation	49709301 49709302 50454301 50454302	Industry Task Force II on 2,4-D Research Data	PAY	
SS-1163 (GDCI)	Honeybee Larval Toxicity	50181701	Industry Task Force II on 2,4-D Research Data	PAY	
870.1100	Acute Oral Toxicity	Cite-All		OLD	
870.1200	Acute Dermal Toxicity	Cite-All		OLD	
870.1300	Acute Inhalation Toxicity	Cite-All		OLD	
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	Jane M. Miller, Agent			08/20/2018	

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Ingredient 2,4-D

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Industry Task Force II on 2,4-D Research Data	PAY	
			Industry Task Force II on 2,4-D Research Data	PAY	
			Industry Task Force II on 2,4-D Research Data	PAY	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
			Industry Task Force II on 2,4-D Research Data	PAY	
			Industry Task Force II on 2,4-D Research Data	PAY	
				OLD	
				OLD	
				OLD	

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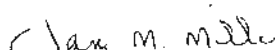
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Applicant's/Registrant's Name & Address ProActive LLC 10529 Heritage Bay Blvd. Naples, FL 34120	Product 2,4-D Acid Technical				
Ingredient 2,4-D					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2400	Primary Eye Irritation	Cite-All		OLD	
870.2500	Primary Dermal Irritation	Cite-All		OLD	
870.2600	Dermal Sensitization	47392101	Dow AgroSciences	PAY	
870.3050	Repeated Dose 28-Day Oral Toxicity Study in Rodents	Cite-All		OLD	
870.3100	90-Day Oral Toxicity (Rodent)	Cite-All		OLD	
870.3150	90-Day Oral Toxicity (Non-Rodent)	Cite-All		OLD	
870.3200	21/28-Day Dermal Toxicity	Cite-All		OLD	
870.3250	90-Day Dermal Toxicity	Cite-All		OLD	
870.3465	90-Day Inhalation Toxicity	47398701 50320801	Industry Task Force II on 2,4-D Research Data	PAY	
870.3550	Reproduction/Developmental Toxicity Screening Test	Cite-All		OLD	
870.3650	Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test	Cite-All		OLD	
870.3700	Prenatal Developmental Toxicity	Cite-All		OLD	
870.3800	Reproduction and Fertility Effects	47972101	Industry Task Force II on 2,4-D Research Data	PAY	
870.4100	Chronic Oral Toxicity	Cite-All		OLD	
870.4200	Carcinogenicity	Cite-All		OLD	
870.5100	Bacterial Reverse Mutation Assay	Cite-All		OLD	
870.5140	Gene Mutation in <i>Aspergillus nidulans</i>	Cite-All		OLD	
870.5195	Mouse Biochemical Specific Locus Test	Cite-All		OLD	
Signature 			Name and Title Jane M. Miller, Agent		Date 08/20/2018

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Product

ProActive LLC 10529 Heritage Bay Blvd. Naples, FL 34120

2,4-D Acid Technical

ingredient 2,4-D

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
				OLD	
				OLD	
			Dow AgroSciences	PAY	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
			Industry Task Force II on 2,4-D Research Data	PAY	
				OLD	
				OLD	
				OLD	
			Industry Task Force II on 2,4-D Research Data	PAY	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
Signature			Name and Title		Date
			Jane M. Miller, Agent		08/20/2018

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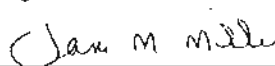
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401 M Street, S.W.

WASHINGTON, D.C. 20460

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DATA MATRIX

Date August 20, 2018	EPA Reg. No./File Symbol 74468-12	Page 10 of 15			
Applicant's/Registrant's Name & Address ProActive LLC 10529 Heritage Bay Blvd. Naples, FL 34120	Product 2,4-D Acid Technical				
Ingredient 2,4-D					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.5200	Mouse Visible Specific Locus Test	Cite-All		OLD	
870.5250	Gene Mutation in <i>Neurospora crassa</i>	Cite-All		OLD	
870.5275	Sex-Linked Recessive Lethal Test in <i>Drosophila melanogaster</i>	Cite-All		OLD	
870.5300	<i>In vitro</i> Mammalian Cell Gene Mutation Test	Cite-All		OLD	
870.5375	<i>In vitro</i> Mammalian Chromosome Aberration Test	Cite-All		OLD	
870.5380	Mammalian Spermatogonial Chromosomal Aberration Test	Cite-All		OLD	
870.5385	Mammalian Bone Marrow Chromosomal Aberration Test	Cite-All		OLD	
870.5395	Mammalian Erythrocyte Micronucleus Test	Cite-All		OLD	
870.5450	Rodent Dominant Lethal Assays	Cite-All		OLD	
870.5460	Rodent Heritable Translocation Assays	Cite-All		OLD	
870.5500	Bacterial DNA Damage or Repair Tests	Cite-All		OLD	
870.5550	Unscheduled DNA Synthesis in Mammalian Cells in Culture	Cite-All		OLD	
870.5575	Mitotic Gene Conversion in <i>Saccharomyces cerevisiae</i>	Cite-All		OLD	
870.5900	<i>In vitro</i> Sister Chromatid Exchange Assay	Cite-All		OLD	
870.5915	<i>In vivo</i> Sister Chromatid Exchange Assay	Cite-All		OLD	
Signature 			Name and Title Jane M. Miller, Agent		Date 08/20/2018

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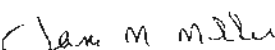
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Applicant's/Registrant's Name & Address ProActive LLC 10529 Heritage Bay Blvd. Naples, FL 34120	Product 2,4-D Acid Technical				
Ingredient 2,4-D					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.6100	Acute and 28-Day Delayed Neurotoxicity of Organophosphorus Substances	Cite-All			11
870.6200	Neurotoxicity Screening Battery	Cite-All		OLD	
870.6300	Developmental Neurotoxicity Study	47972101	Industry Task Force II on 2,4-D Research Data	PAY	
870.6500	Schedule-Controlled Operant Behavior	Cite-All			12
870.6850	Peripheral Nerve Function	Cite-All			12
870.6855	Neurophysiology: Sensory Evoked Potentials	Cite-All			12
870.7200	Companion Animal Safety	Cite-All			13
870.7485	Metabolism and Pharmacokinetics	Cite-All			14
870.7600	Dermal Penetration	46589401	Industry Task Force II on 2,4-D Research Data	PAY	
870.7800	Immunotoxicity	47972101	Industry Task Force II on 2,4-D Research Data	PAY	
870.8340	Oral and Inhalation Pharmacokinetic Test	Cite-All		OLD	
870.8355	Combined Chronic Toxicity/Carcinogenicity Testing of Respirable Fibrous Particles	Cite-All			15
870.8360	Pharmacokinetics of Isopropanol	Cite-All			16
870.8380	Inhalation and Dermal Pharmacokinetics of Commercial Hexane	Cite-All			17
870.8500	Toxicokinetic Test	Cite-All			18
870.8600	Developmental Neurotoxicity Screen	47972101	Industry Task Force II on 2,4-D Research Data	PAY	
870.8700	Subchronic Oral Toxicity	Cite-All		OLD	
870.8800	Morphologic Transformation of Cells in Culture	Cite-All			19
Signature 			Name and Title Jane M. Miller, Agent		Date 08/20/2018

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DATA MATRIX

Date August 20, 2018

EPA Reg. No./File Symbol 74468-12

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Applicant's/Registrant's Name & Address

Product

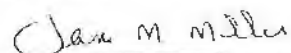
ProActive LLC 10529 Heritage Bay Blvd. Naples, FL 34120

2,4-D Acid Technical

Ingredient 2,4-D

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					11
				OLD	
			Industry Task Force II on 2,4-D Research Data	PAY	
					12
					12
					12
					13
					14
			Industry Task Force II on 2,4-D Research Data	PAY	
			Industry Task Force II on 2,4-D Research Data	PAY	
				OLD	
					15
					16
					17
					18
			Industry Task Force II on 2,4-D Research Data	PAY	
				OLD	
					19

Signature



Name and Title

Jane M. Miller, Agent

Date

08/20/2018

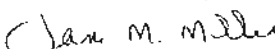
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DATA MATRIX

Date August 20, 2018		EPA Reg. No./File Symbol 74468-12		Page 12 of 15	
Applicant's/Registrant's Name & Address ProActive LLC 10529 Heritage Bay Blvd. Naples, FL 34120		Product 2,4-D Acid Technical			
Ingredient 2,4-D					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.1100	Dermal Exposure – Outdoor (Residential)	Cite-All		OLD	
875.1200	Dermal Exposure - Indoor				20
875.1300	Inhalation Exposure – Outdoor (Residential)	Cite-All		OLD	
875.1400	Inhalation Exposure – Indoor				20
875.1500	Biological Monitoring (Residential)	Cite-All		OLD	
875.1600	Application Exposure Monitoring (Residential)	Cite-All		OLD	
875.2100	Foliar Dislodgeable Residue Dissipation (Residential)	Cite-All		OLD	
875.2200	Soil Residue Dissipation (Residential)	Cite-All		OLD	
875.2400	Dermal Exposure (Residential)	Cite-All		OLD	
875.2500	Inhalation Exposure (Residential)	Cite-All		OLD	
875.2600	Biological Monitoring (Residential)	Cite-All		OLD	
875.2800	Descriptions of Human Activity (Residential)	Cite-All		OLD	
75.2900	Data Reporting and Calculations	50631118	ProActive, LLC	OWN	
890.1100	Amphibian Metamorphosis (Frog)	48317002	Dow AgroSciences	PAY	
890.1150	Androgen Receptor Binding (Rat Prostrate Cytosol)	48091601	Industry Task Force II on 2,4-D Research Data	PAY	
890.1200	Aromatase (Human Recombinant)	48091601	Industry Task Force II on 2,4-D Research Data	PAY	
890.1250	Estrogen Receptor Binding (Rat Uterine Cytosol)	48091601	Industry Task Force II on 2,4-D Research Data	PAY	
890.1300	Estrogen Receptor Transcriptional Activation (Human Cell Line (HeLa -9903))	48091601	Industry Task Force II on 2,4-D Research Data	PAY	
Signature 			Name and Title Jane M. Miller, Agent		Date 08/20/2018

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DATA MATRIX

Date August 20, 2018

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Page 12 of 15


Applicant's/Registrant's Name & Address

ProActive LLC 10529 Heritage Bay Blvd. Naples, FL 34120

Product

2,4-D Acid Technical

Ingredient 2,4-D

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
				OLD	
					20
				OLD	
					20
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
				OLD	
			ProActive, LLC	OWN	
			Dow AgroSciences	PAY	
			Industry Task Force II on 2,4-D Research Data	PAY	
			Industry Task Force II on 2,4-D Research Data	PAY	
			Industry Task Force II on 2,4-D Research Data	PAY	
			Industry Task Force II on 2,4-D Research Data	PAY	
Signature			Name and Title		Date
			Jane M. Miller, Agent		08/20/2018

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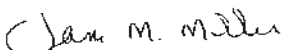
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DATA MATRIX

Date August 20, 2018	EPA Reg. No./File Symbol 74468-12	Page 13 of 15			
Applicant's/Registrant's Name & Address ProActive LLC 10529 Heritage Bay Blvd. Naples, FL 34120		Product 2,4-D Acid Technical			
Ingredient 2,4-D					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
890.1350	Fish Short-Term Reproduction	48317001	Dow AgroSciences	PAY	
890.1400	Hershberger (Rat)	48091601	Industry Task Force II on 2,4-D Research Data	PAY	
890.1450	Female Pubertol (Rat)	48091601	Industry Task Force II on 2,4-D Research Data	PAY	
890.1500	Male Pubertol (Rat)	48091601	Industry Task Force II on 2,4-D Research Data	PAY	
890.1550	Steroidogenesis (Human Cell Line H295R)	48091601	Industry Task Force II on 2,4-D Research Data	PAY	
890.1600	Uterotrophic (Rat)	48091601	Industry Task Force II on 2,4-D Research Data	PAY	
890.2100	Avian Two-Generation Toxicity Test in the Japanese Quail				21
890.2200	Medaka Extended One Generation Reproduction Test				21
890.2300	Larval Amphibian Growth and Development Assay				21
Signature 			Name and Title Jane M. Miller, Agent		Date 08/20/2018

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DATA MATRIX

Date August 20, 2018	EPA Reg. No./File Symbol 74468-12	Page 13 of 15			
Applicant's/Registrant's Name & Address ProActive LLC 10529 Heritage Bay Blvd. Naples, FL 34120	Product 2,4-D Acid Technical				
Ingredient 2,4-D					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Dow AgroSciences	PAY	
			Industry Task Force II on 2,4-D Research Data	PAY	
			Industry Task Force II on 2,4-D Research Data	PAY	
			Industry Task Force II on 2,4-D Research Data	PAY	
			Industry Task Force II on 2,4-D Research Data	PAY	
			Industry Task Force II on 2,4-D Research Data	PAY	
					21
					21
					21
Signature <i>Jane M. Miller</i>	Name and Title Jane M. Miller, Agent			Date 08/20/2018	

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DATA MATRIX FOOTNOTES

1. Description of Formulation Process: Not applicable because the product is a TGA/MP.
2. Submittal of Samples: Not required at this time.
3. Flammability / Flame Extension: Not applicable. Product does not contain combustible liquids.
4. Explodability: Not applicable. Product is not potentially explosive.
5. Miscibility: Not applicable. Product is not intended for dilution with petroleum solvents.
6. Dielectric Breakdown Voltage: Not applicable. Product is not intended for use around electrical equipment.
7. Viscosity: Not required because product is a solid.
8. Mysid Chronic Toxicity: EPA waived this requirement (ref. April 12, 2013 Memorandum "EFED Registration Review Problem Formulation for 2,4-D – REVISED").
9. Oyster and Fish Bioconcentration: EPA waived this requirement given the low value of the log *n*-octanol/water partition coefficient (log K_{ow} 0.18 at neutral pH). (ref. June 29, 2016 Memorandum "Preliminary Ecological Risk Assessment for Registration Review of 2,4-D" and April 12, 2013 Memorandum "EFED Registration Review Problem Formulation for 2,4-D – REVISED").
10. Honeybee Toxicity of Residues on Foliage and Field Testing for Pollinators: Not required for Registration Review at this time (ref. June 29, 2016 Memorandum "Preliminary Ecological Risk Assessment for Registration Review of 2,4-D" and April 12, 2013 Memorandum "EFED Registration Review Problem Formulation for 2,4-D – REVISED").
11. Acute and 28-Day Delayed Neurotoxicity of Organophosphorus Substances: Not required because the product is not an organophosphorus substance.
12. Schedule-Controlled Operant Behavior, Peripheral Nerve Function and Neurophysiology: Sensory Evoked Potential: Not required for Registration Review at this time (ref. September 27, 2017 Memorandum "2,4-D. Revised Human Health Assessment for Registration Review").
13. Companion Animal Safety: Not required because the product is not intended for application to companion animals.
14. Metabolism and Pharmacokinetics: The biotransformation of this compound is not expected to change qualitatively and quantitatively from oral and inhalation routes of exposure. Not required for Registration Review at this time (ref. September 27, 2017 Memorandum "2,4-D. Revised Human Health Assessment for Registration Review").

DATA MATRIX FOOTNOTES (continued)

15. Combined Chronic Toxicity/Carcinogenicity Testing of Respirable Fibrous Particles: Not required because the product does not contain fibrous particles.
16. Pharmacokinetics of Isopropanol: The biotransformation of this compound is not expected to change after oral and inhalation routes of exposure. Not required for Registration Review at this time (ref. September 27, 2017 Memorandum “2,4-D. Revised Human Health Assessment for Registration Review”).
17. Inhalation and Dermal Pharmacokinetics of Commercial Hexane: The biotransformation of this compound is not expected to change after dermal and inhalation routes of exposure. Not required for Registration Review at this time (ref. September 27, 2017 Memorandum “2,4-D. Revised Human Health Assessment for Registration Review”).
18. Toxicokinetic Test: The biotransformation of this compound is not expected to change after dermal and oral routes of exposure. Not required for Registration Review at this time (ref. September 27, 2017 Memorandum “2,4-D. Revised Human Health Assessment for Registration Review”).
19. Morphologic Transformation of Cells in Culture: Not required for Registration Review at this time (ref. September 27, 2017 Memorandum “2,4-D. Revised Human Health Assessment for Registration Review”).
20. Dermal Exposure – Indoor and Inhalation Exposure – Indoor: Not required because the product is not intended for indoor use.
21. Avian Two-Generation Toxicity Test in the Japanese Quail, Medaka Extended One Generation Reproduction Test and Larval Amphibian Growth and Development Assay: Tier 2 endocrine disruption tests are not required at this time.



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Washington, DC 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address and Telephone Number ProActive, LLC 10529 Heritage Bay Blvd. Naples, FL 34120 jmillers@biologicconsulting.com	EPA Registration Number/File Symbol 74468-12
Active Ingredient(s) and/or Representative Test Compound(s) 2,4-D Acid	Date August 29, 2018
General Use Pattern(s) [list all those claimed for this product using 40 CFR Part 158] Terrestrial nonfood, aquatic nonfood, residential outdoor	Product Name 2,4-D Acid Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data Call-In Notice and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

Section I: Method of Data Support
 (Check only one method)

- | | |
|---|---|
| <input type="checkbox"/> I am using the cite-all method of support and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose). | <input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method) and have included with this form a completed list of data requirements (the Data Matrix form must be used). CSI has conducted some data and made OTP letters for studies specified on the data matrix. |
|---|---|

Section II: General Offer-to-Pay

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation to other persons with regard to the approval of this application to the extent required by FIFRA. **Must be checked for either of the above option.**

Section III: Certification

I hereby certify that this application for registration, this form for reregistration or this Data Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration or the Data Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered: (i) to pay compensation to the extent required by Sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with Sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 08/29/2018	Typed or Printed Name and Title Jane M. Miller, Agent
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DOCUMENTUM



Receipt

Your payment is submitted

Pay.gov Tracking ID: 26BV4FN2

Agency Tracking ID: 75563716334

Form Name: Pesticide Registration Improvement Act - Prepayment

Application Name: PRIA Service Fees

Payment Information

Payment Type: Bank account (ACH)

Payment Amount: \$13,226.00

Transaction Date: 08/31/2018 03:05:30 PM EDT

Payment Date: 09/04/2018

Registration Number: 74468-12

Company Name: ProActive LLC

Company Number: 74468

Action Code: R351

Account Information

Account Holder Name: ProActive LLC

Routing Number: 272480678

Account Number: *****9120

Email Confirmation Receipt

Confirmation Receipts have been emailed to:

jmill@biologicconsulting.com

jmill@biologicconsulting.com

Material Sent for Data Extraction

Reg. # 74468-12

Description: Notice of Registration

☐ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 8/21/12

☐ Notification Dated _____

☐ New CSF(s) Dated _____

☐ Other: _____

☒ Decision #: 464.325

☒ Other Action/Comments: _____
Copy onto PPLS

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Dianne L. Morgan

Phone: 305-6217 Division: RD

Date: 8/24/12



**U.S. ENVIRONMENTAL PROTECTION
AGENCY**

**Office of Pesticide Programs
Registration Division (7505P)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460**

**EPA Registration
Number:**

74468-12

Date of Issuance:

AUG 21 2012

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

2,4-D Acid Technical

Name and Address of Registrant (include ZIP Code):

ProActive, Inc.
c/o Biologic, Inc.
115 Obtuse Hill Road
Brookfield, CT 06804

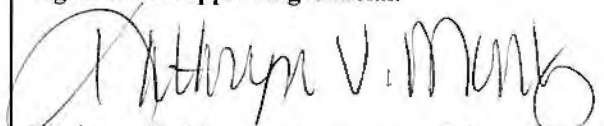
Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is registered in accordance with FIFRA sec. 3 (c) (7) (A) provided that you:

1. Submit and/or cite all data required for the registration/ reregistration review of your product when the Agency requires all registrants of similar products to submit data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. Change the EPA Registration Number to read: "74468-12"
3. Add "To the extent consistent with applicable law...", to the warranty statement in front of "proactive" in the second paragraph.
4. Submit one (1) copy of the revised final printed label before the product is released for shipment.

Signature of Approving Official:


Kathryn V. Montague, Product Manager 23
Herbicide Branch
Registration Division (7505P)

Date:

AUG 21 2012

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records. If you have any questions, contact Dianne L. Morgan of my team at (703) 305-6217.

2,4-D Acid Technical

For Manufacturing Use Only

Active Ingredient:
2,4-dichlorophenoxyacetic acid98.2%
Related Ingredients:..... 1.8%
Total.....100.0%

ACCEPTED
with COMMENTS
In EPA Letter Dated:

AUG 21 2012

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

74468-12

Keep Out of Reach of Children DANGER

Precautionary Statements

Hazards to Humans and Domestic Animals

Corrosive. Causes irreversible eye damage. Harmful if swallowed, inhaled or absorbed through the skin.

Do not get in eyes or on clothing. Avoid contact with skin or clothing. Avoid breathing vapor. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. When handling this product, wear eye protection (safety glasses, face shield, or chemical goggles), and chemical resistant gloves (nitrile rubber or butyl rubber ≥ 14 mils). Remove and wash contaminated clothing and clean protective equipment before reuse.

First Aid	
If in eyes:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If swallowed:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If on skin or clothing:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If inhaled:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth if possible.• Call a poison control center or doctor for further treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may contact 1-800-222-1222 for emergency medical treatment information.	
Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.	

Manufacturing Chemical: Do not ship or store with food, feeds, drugs or clothing.

Environmental Hazards

This product is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Directions for Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For Manufacturing Use Only

For Formulation Into An Herbicide for Use Only On The Following Crops:

1. **Agricultural Crops:** Corn (Field, Pop and Sweet), Small Grains (Barley, Millet, Oats, Rye, and Wheat), Rice, Sorghum (Grain and Forage, Milo), Soybeans (preplant), Sugarcane, Grass Pastures, Rangeland, Fallow Cropland, Grass Seed Crops, Crop Stubble, Annual Grasses, Perennial Grasses, Asparagus, Cranberries, Grapes (only in California), Hops, Orchard Floors (Pome Fruits, Citrus Fruit, and Nut Crops; Stone Fruit, Filberts); Potatoes (fresh market only); Strawberry, Blueberry.

For The Following Non-Crop Uses: Turf (including Lawns, Golf Courses, Cemeteries, Parks, Airfields, Yards), Roadsides, Non-Cropland Areas including Rights-of-Way, Areas in the Conservation Reserve Program, Railroads, Drainage Ditch Banks, Fence Rows, Tree Injection Treatments, Woody Plant Control in Non-Cropland Areas; Ornamental Trees, Shrubs and Vines; Forestry, grass seed crops, sod production;

Aquatic Weed Control: agricultural irrigation water and ditches; agricultural drainage water and ditches; lakes, ponds, reservoirs, impounded water, streams, rivers, and canals; swamps, marches, wetlands, estuaries, tidal marshes; commercial and sport fish bearing waters; industrial ponds;

Forestry: forest trees, plantings, forest tree nurseries, forest site preparation, forest roadsides, tree and brush control, established conifer release, Christmas trees, reforestation areas, tree injection treatments.

2. Uses for which U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration.
3. Uses for experimental purposes that are in compliance with U.S. EPA requirements.

This product may be used to formulate products for specific use(s) not listed on this label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding support of such use(s).

Formulators using this product are responsible for obtaining EPA registration for their formulated products. Contact ProActive, LLC for instructions about formulation and other information.

Wettable powder formulations must be packaged in water-soluble packages.

Storage and Disposal

Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited.

Pesticide Storage: Keep container tightly closed when not in use. This product can be stored in an unheated building.

Pesticide Disposal: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law and may contaminate groundwater. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or environmental control agency, or the hazardous waste representative at the nearest EPA regional office for guidance.

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into formulation equipment. Then offer for recycling, if available, or dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. Consult federal, state, or local disposal authorities for approved alternative procedures.

Warranty Limitations and Disclaimer

ProActive, LLC warrants that at the time of delivery, the product will conform to its chemical description on the label, that it will pass without objection in the trade under the contract description, that seller will convey good title thereto, and that such product will be delivered free from any lawful security interest, lien or encumbrance.

This is the only warranty made on this product. ProActive, LLC EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND, EXCEPT AS SET FORTH IN THE ABOVE PARAGRAPH, ANY OTHER EXPRESS OR IMPLIED WARRANTIES. Buyer acknowledges the use of its own independent skill and expertise in the selection and use of the product and does not rely on any oral or written statements or representations.

Manufacturing Chemical: Do not ship or store with food, feeds, drugs or clothing.

EPA Reg. No. 74468-XX

EPA Est. Nos. 83227-CHN-001
72951-CHN-001

Net Weight: 1,764 lbs. (800 kg)
Batch No. [marked on container]

Manufactured for:
ProActive, LLC
P.O. Box 5068
Brookfield, CT 06804



21-Day Screen Completed by
Contractor

21-Day Expires on 5/21/12

Jacket # 74468-RE
MRID# NA

Content Screen: Recommend to Pass/Fail

11-3 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

Steve Schiavle

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 4-30-12

Experts In-Processing Signature: MF HARRINGTON Date 5-2-12 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>74468-RE</u>		EPA Receipt Date: <u>4-30-12</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to http://www.epa.gov/oppr001/inerts/), including fragrances, approved for the proposed uses (see Footnote A) <u>100% Repack</u>	yes	no			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)					X
	Certificate and data matrix consistent					
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
5	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)					X
	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (link to http://www.epa.gov/oppead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)			X
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

- * AI + % Composition was added
- * CSF Approved: 100% reject, no inerts to review
- * No Study Submitted
- * Jacket approved.

NRID: N/A

IK S-4812
AB

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

R 300 and 301

100% identical (repack): YES or NO (circle one)

{If **yes**, it's a 100% repack - then product chemistry, acute toxicity and efficacy data are not required}

Data on Group and A and B must be submitted - Group A and B can not be cited.

Guideline No.	Group A: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.1550	Product Identity & Composition		
830.1600	Description of materials used to produce the product		
830.1650	Description of formulation process		
830.1670	Discussion on the formation of impurities		
830.1700	Preliminary analysis		
830.1750	Certified limits (158.345)		
830.1800	Enforcement analytical method		

Guideline No.	Group B: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.6302	Color		
830.6303	Physical State		
830.6304	Odor		
830.6314	Oxidation/Reduction (Chemical incompatibility)		
830.6315	Flammability		
830.6316	Explosibility		
830.6317	Storage stability		
830.6319	Miscibility		
830.6320	Corrosion Characteristics		
830.6321	Dielectric Breakdown voltage		
830.7000	pH		
830.7100	Viscosity		
830.7300	Density		

R 300 and JJ1

New products must provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Cited	
		Yes	No
870.1100	Acute Oral (LD50)		
870.1200	Acute Dermal (LD50)		
870.1300	Acute Inhalation (LC50)		
870.2400	Acute Eye Irritation		
870.2500	Acute Dermal Irritation		
870.2600	Dermal Sensitization		

Efficacy – which guideline depends on the proposed label use and they must cite the data to be used for the bridging rationale.

Guideline No.	Efficacy Study Titles	Cited		Comments
		Yes	No	
810.3100	Soil Treatments for Imported Fire Ants			
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments			
810.3300	Treatments to Control Pests of Humans and Pets			
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments			
810.3500	Premises Treatments			
810.3600	Structural Treatments			
810.3800	Methods for Efficacy Testing of Termite Baits			



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 1, 2012

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-464325
EPA File Symbol or Registration Number: 74468-RE
Product Name: 2,4-D ACID TECHNICAL
EPA Receipt Date: 30-Apr-2012
EPA Company Number: 74468
Company Name: PROACTIVE LLC

JANE M. MILLER
BIOLOGIC, INC.
PROACTIVE LLC
115 OBTUSE HILL ROAD
BROOKFIELD, CT 06804

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R300

NEW PRODUCT;ME-TOO PRODUCT FAST TRACK;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "m/26", is written over the word "Sincerely,".

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{916036\$~

This package includes the following

- ☒ New Registration
- ☐ Amendment

- ☐ Studies? ☐ Fee Waiver?
- ☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 23

Receipt No.

S-

916036

EPA File Symbol/Reg. No.

74468-RE

Pin-Punch Date:

4/30/2012

- ☐ This item is NOT subject to FFS action.

Action Code:

Requested: R300

Granted: R300

Amount Due: \$ 1,434

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Jennifer Gaines

Date: 5/1/12

Remarks:

Receipt for Section 3

S: 916036

Regulatory Type: Product Registration - Section 3

Application Type: New Registration

Company: 74468 PROACTIVE LLC

Risk Manager: Registration Division, Risk Management Team 23

Product #: 74468-RE

Product Name: 2,4-D ACID TECHNICAL

Override#:

Me Too Section3:

Me Too Product Name:

Application Date: 27-Apr-2012

Front End Date: 30-Apr-2012

FFS Due Date:

OPP Target Date:

Fast Track:

Receipt Description: New pesticide product

Form A:

Signature Date:

Resubmission: Yes No

Fee For Service: Yes No

Billable: Yes No

V

OPP Rec'vd Date: 30-Apr-2012

Risk Manager Send Date:

Negotiated Due Date:

New Ingredient:

Form B:

Signature Date:

New Ingredient Request Date:

New Ingredient Received Date:

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content	Des
CSF	
Paper Label	

View/Edit

Jane Miller

From: paygovadmin@mail.doc.twai.gov
Sent: Friday, April 27, 2012 1:42 PM
To: jrmiller@biologicconsulting.com
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Pay.gov Customer Service by phone at (800) 624-1373 or by email at pay.gov.clev@clev.frb.org.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 256GGOKF
Agency Tracking ID: 74306839185
Transaction Type: Sale
Transaction Date: Apr 27, 2012 1:41:33 PM

Account Holder Name: Lawrence A. Miller
Transaction Amount: \$1,434.00
Billing Address: 115 Obtuse Hill Road
City: Brookfield
State/Province: CT
Zip/Postal Code: 06804
Country: USA
Card Type: Visa
Card Number: *****2063

Decision Number:
Registration Number:
Company Name: ProActive, LLC
Company Number: 74468
Action Code: R300

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

21-04-27

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Please read instructions on reverse before completing form.

Form Approved

OMB No. 2070-0060, Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 74468-XX <i>RE</i>	2. EPA Product Manager K. Montague	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) 2,4-D Acid Technical	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) ProActive, LLC c/o Biologic, Inc. 115 Obtuse Hill Road Brookfield, CT 06804 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. [REDACTED] Product Name [REDACTED]	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This application for a new pesticide product will fall within the category on Table 4 - Registration Division: New Products as published in the August 2008 Federal Register. This product is further defined under EPA No. 300; CR No. 44. This product is a "Re-Pack". The PRIA fee for this application is \$1,434.

Jane Miller Tel: (203) 740-1200; Fax: (203) 740-1220; Email: jmillar@biologicconsulting.com

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) poly bag	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1,764 lbs. (800 kg.)		5. Location of Label Directions <input checked="" type="checkbox"/> on label	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Jane M. Miller	Title Agent	Telephone No. (Include Area Code) 203-740-1200
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent	
4. Typed Name Jane M. Miller	5. Date April 27, 2012	

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April 27, 2012

Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Room S-4900, 4th Floor
Arlington, VA 22202

Attention: Ms. Kathryn Montague (PM #23)

RE: "2,4-D Acid Technical", EPA Reg. No. 74468-XX
Application for Pesticide Registration – Re-Pack

Dear Ms. Montague:

On behalf of ProActive, LLC we are submitting this Application for Pesticide Registration for the above mentioned product. The subject product is a 100% "re-pack" of [REDACTED]

The following documents are enclosed to process this registration:

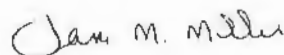
Volume I Administrative Materials

- Application for Pesticide Registration (EPA Form 8570-1)
- Formulator's Exemption Statement (EPA Form 8570-27)
- Confidential Statement of Formula (EPA Form 8570-4)
- Five (5) copies of draft labeling

This application for a new pesticide product will fall within the category on Table 4 - Registration Division: New Products, EPA No. R300; CR No. 44. The PRIA fee for this application is \$1,434.

Should you have any questions, or wish to reach me, please feel free to contact our office at 203-740-1200.

Sincerely,



Jane M. Miller
Agent to ProActive, LLC

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United States

Environmental Protection Agency

Washington, DC 20460

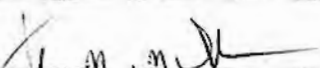
Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address ProActive, LLC c/o Biologic, Inc. 115 Obtuse Hill Road Brookfield, CT 06804	EPA File Symbol/Registration Number 74468-XX
	Product Name 2,4-D Acid Technical
	Date of Confidential Statement of Formula (EPA Form 8570-4) April 27, 2012

As an authorized representative of the applicant for registration of the product identified above, I certify that:

- (1) This product contains the following active ingredient(s):
2,4-D Acid Technical
- (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.
- (3) Indicate by checking (A) or (B) below which paragraph applies:
- ☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).
- OR
- ☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.
- (4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
2,4-D Acid Technical		
Signature 	Name and Title Jane M. Miller, Agent	Date 4/30/12

Product ingredient source information may be entitled to confidential treatment

